

**A COMPARATIVE STUDY OF DEXMEDETOMIDINE
VS FENTANYL AS AN ANAESTHETIC ADJUVANT IN
ANAESTHESIA FOR COCHLEAR IMPLANTATION
IN PAEDIATRIC PATIENTS DOUBLE BLINDED
CONTROL STUDY**

Dissertation submitted to

THE TAMILNADU DR.M.G.R.MEDICAL UNIVERSITY

In partial fulfillment for the award of the degree of

**DOCTOR OF MEDICINE
IN ANAESTHESIOLOGY
BRANCH X**



**INSTITUTE OF ANAESTHESIOLOGY & CRITICAL CARE
MADRAS MEDICAL COLLEGE
CHENNAI 600 003**

APRIL 2018

CERTIFICATE

This is to certify that the dissertation entitled
**“A COMPARATIVE STUDY OF DEXMEDETOMIDINE
VERSUS FENTANYL AS AN ANAESTHETIC ADJUVANT IN
ANAESTHESIA FOR COCHLEAR IMPLANTATION IN
PAEDIATRIC PATIENTS: DOUBLE BLINDED CONTROL
STUDY”** submitted by Dr.Azmal khan.A in partial fulfillment for
the award of the degree of Doctor of Medicine in Anaesthesiology
by the Tamilnadu Dr.M.G.R.Medical University,Chennai is
bonafide record of the work done by him in the INSTITUTE OF
ANAESTHESIOLOGY & CRITICAL CARE, Madras Medical
College, during the academic year 2015-2018.

Prof.Dr.ANURADHA SWAMINATHAN, MD., DA.,
Professor and Director,
Institute of Anesthesiology &
Critical Care,
Madras Medical College,
Rajiv Gandhi Govt General Hospital,
Chennai – 600003.

Prof.Dr.R.NARAYANA BABU, MD, DCH
The Dean,
Madras Medical College,
Rajiv Gandhi Govt General
Hospital,Chennai – 600003.

CERTIFICATE OF GUIDE

This is to certify that the dissertation entitled
**“A COMPARATIVE STUDY OF DEXMEDETOMIDINE
VERSUS FENTANYL AS AN ANAESTHETIC ADJUVANT IN
ANAESTHESIA FOR COCHLEAR IMPLANTATION IN
PAEDIATRIC PATIENTS: DOUBLE BLINDED CONTROL
STUDY”** Submitted by Dr.Azmal Khan.A in partial fulfillment for
the award of the degree of Doctor of Medicine in Anaesthesiology
by the Tamilnadu Dr M.G.R.Medical University, Chennai is
bonafide record of the work done by him in the INSTITUTE OF
ANAESTHESIOLOGY & CRITICAL CARE, Madras Medical
College, during the academic year 2015-2018

PROF.DR.M.VELLINGIRI MD,DA.,
Professor
Department of Anaesthesiology,
Institute of Anaesthesiology &
Critical Care,
Madras Medical College,
Chennai 600 003.

Date :

Place: Chennai.

DECLARATION

I, Dr.A.Azmal Khan,solemnly declare that the dissertation **“A COMPARATIVE STUDY OF DEXMEDETOMIDINE VERSUS FENTANYL AS AN ANAESTHETIC ADJUVANT IN ANAESTHESIA FOR COCHLEAR IMPLANTATION IN PAEDIATRIC PATIENTS: DOUBLE BLINDED CONTROL STUDY”** is a bonafide work done by me in the Institute of Anaesthesiology & Critical Care, Madras Medical College,Chennai, after getting approval from the Ethical Committee,under the able guidance of **Prof.Dr.M.VELLINGIRI MD, DA.,** Institute of Anaesthesiology & Critical Care, MMC,Chennai. This study was conducted in Institute of It or him O’Leary go logy,Chennai,in partial fulfillment of the regulations for the award of the degree of MD Anaesthesiology examination to be held in April 2018.

I have not submitted this dissertation previously to any journal or any university for the award of any degree or diploma.

DR.A.AZMAL KHAN

Date :

Place : Chennai

ACKNOWLEDGEMENT

On completion of my dissertation I would like to acknowledge all those who have made this possible.

I am extremely thankful to **Dr.NARAYANA BABU MD, DCH.**, Dean, Madras Medical College, for his kind permission to carry out this study.

I am immensely grateful to **PROF.DR.ANURADHA SWAMINATHAN MD,DA.**, Director & Professor, Institute Of Anaesthesiology & Critical Care, for her concern and support in conducting this study.

I am extremely grateful and indebted to my guide **PROF.DR.M.VELLINGIRI MD, DA.**, Professor of Anaesthesiology, Institute of Anaesthesiology & Critical Care, for his concern,inspiration,meticulous guidance,expert advice and constant encouragement in preparing this dissertation.

I am extremely thankful to my co-guide **Dr.CATHERINE RATHINASAMY MD.**, Assistant Professor of Anaesthesiology, Institute of Anaesthesiology And Critical Care for her constant support and help in my dissertation work.

I am very much indebted to all my **Assistant Professors**, Department of Anaesthesiology, Institute of Anaesthesiology & Critical Care, Chennai, for their inspiration, invaluable guidance and supervision at all stages of this study.

I would like to express my thanks to the **staff members** of the Institute of Anaesthesiology & Critical Care, Chennai, for their ever willing help and cooperation during the course of this study.

I would like to thank all my **colleagues and friends** for their whole hearted help and advice in carrying out this study.

I am grateful to my **family and friends** for their moral support and encouragement.

Last but not the least, I am extremely grateful to **all my patients parents or guardians** who inspite of all their sufferings have lent themselves to be a very valuable part of this study and have helped me to improve my knowledge and complete this dissertation.

Above all I pay my gratitude to the **ALMIGHTY** for giving me strength to complete my work.

INDEX

S. No	Contents	Page No
1.	INTRODUCTION	1
2.	AIM OF THE STUDY	2
3.	ANATOMY OF PAEDIATRIC AIRWAY	3
4.	REVIEW OF LITERATURE	21
5.	MATERIALS AND METHODS	36
6.	OBSERVATION AND RESULTS	45
7.	STATISTICS	46
8.	DISCUSSION	69
9.	SUMMARY	75
10.	CONCLUSION	76
11.	BIBLIOGRAPHY	
12.	ANNEXURES a. Ethical Committee approval b. Antiplagarism –URKUND Copy c. Plagarism Certificate d. Patient Consent Form e. Patient Information Form f. Proforma g. Master Chart	

INTRODUCTION

General anaesthesia is the induction of state of complete unconsciousness with loss of pain sensation over the entire body. The purpose of general anaesthesia are analgesia, amnesia, immobility, unconsciousness, skeletal muscle relaxation. Infants and young children respond to medications due to factors like body composition, protein binding, body temperature distribution of cardiac output, functional maturity of the liver and kidneys.

Cochlear implantation surgery is a great advance in otology for patients with irreversible hearing loss. Anaesthetic management includes bloodless surgical field to facilitate microsurgery, efficient airway management, smooth recovery and post operative care without nausea and vomiting.

The study was designed to evaluate the post operative recovery time by using infusion dose of Dexmedetomidine 0.4mcg/kg/hr versus Fentanyl 1mcg/kg/hr in patients undergoing cochlear implantation surgery.

AIM OF THE STUDY

- ❖ To compare the post operative recovery time by modified aldrete recovery score using Dexmedetomidine and Fentanyl in cochlear implantation surgery for pediatric patients.
 - ❖ To assess post operative pain by FLACC behavioural pain assessment scale
 - ❖ To assess intraoperative hemodynamics.
 - ❖ To assess the quality of the surgical field.
 - ❖ To assess need for rescue analgesia and antiemetic in PACU.
- General Anaesthesia: Paediatric patients present unique anatomic, physiologic and pharmacologic consideration for the management of anaesthesia.

ANATOMY OF PAEDIATRIC AIRWAY

Paediatric airway is more susceptible to upper airway obstruction because of large occiput which cause neck flexion, large tongue, increased soft tissue and flexible trachea can produced pressure on the tracheal ring leading to obstruction, cricoid pressure can cause tracheal collapse and obstruction. Visualization of airway and endotracheal intubation is difficult because of large tongue high and more anterior airway, more acute angle between tracheal opening and epiglottis, narrowest diameter at cricoid ring high and anterior larynx at level of C3-C4.

GUEDEL'S STAGES OF ANAESTHESIA

Stage-I (Stage of analgesia or discrimination) from beginning of induction of general anaesthesia to loss of consciousness.

Stage-II (Stage of excitement or delirium) from loss of consciousness to onset of automatic breathing. Eyelash reflex disappear but other reflexes remain intact.

Stage-III (Stage of surgical anaesthesia) from onset of automatic respiration to respiratory paralysis.

Stage-IV from stoppage of respiration till death. Anaesthetic overdose cause medullar paralysis with respiratory arrest and vasomotor collapse.

CHOICE OF ANAESTHESIA

General Anaesthesia preferred due to

- Surgery under microscope visualisation
- Pediatric patients
- Long duration of surgery

ADVANTAGES OF GENERAL ANAESTHESIA

- ❖ Reduces intraoperative awareness and recall.
Complete control of the airway breathing.
- ❖ Can be reversible.
- ❖ Allow proper muscle relaxation.

DISADVANTAGES OF GENERAL ANAESTHESIA

Can induce physiologic fluctuations that require active intervention.

Associated with loss serious complication such as nausea or vomiting, sore throat, shivering, headache, delayed return to normal mental functioning.

PAEDIATRIC VITAL SIGNS

Age	Pulse/min	Respiration	Systolic BP mmHg
Birth-6 months	140-150	40	60-80
6 month-1 year	110-140	30-40	80-90
1-3 years	100-110	25-30	90
3-4 years	95-100	25	100
5-10 years	90-95	24	100-110

NPO GUIDELINES

Age	Fasting time	
	Milk and Solids(hr)	Clear Fluids (hr)
<6 months	4	2
6 months- 3years	6	3
>3 years	8	3

PRE OPERATIVE ASSESSMENT

- Presence of any congenital abnormalities
- Cerebral palsy
- Developmental milestones
- Active upper respiratory infections
- Any neuromotor deficits

Premedication

The goal of premedication are to facilitate a smooth separation from the parents, to have the patient arrive in the operating room in a calm, relaxed frame of mind. Effects achieved by premedication include anxiolysis, prevention of physiologic stress, decreased salivation and secretions and antiemesis.

INDUCTION

Induction can be achieved by intravenous injection of induction agents, by the slower inhalation of anaesthetic vapour delivered into a face mask or by a combination of both. Sevoflurane (fluoromethyl 2,2,2-trifluoro-1-(trifluoromethyl) ethyl ether an inhalational anaesthetic agent with low blood solubility,

less pungent. Induction of anaesthesia is more rapid and recovery is also more rapid.

Propofol (2,6-diisopropylphenol) exerts hypnotic actions by activation of the central inhibitory neurotransmitter GABA. An induction dose of 2-2.5mg/kg produces a 25% to 40% reduction of systolic blood pressure, mean and diastolic blood pressure. This effect is due to arterial vasodilation due to reduced vascular sympathetic tone.

Intubation

Laryngoscopy and tracheal intubation in anaesthetized children is associated with hypertension and tachycardia due to reflex sympathetic activation. Endotracheal tube placement should be confirmed by auscultation and end tidal capnography.

Formula for selection of endotracheal tube

For children <6 year of age = $\text{Age}/3 + 3.5 = \text{ETT ID in mm}$

Depth of insertion for oral ETT = $10.5 + \text{wt (kg)}/2$

or Age + 10cm

Maintenance of intraoperative IV fluids.

Holliday and segar formula

0-10kgs : 4ml/kg/hr

10-20kgs : 40+2ml/kg/hr

>20 Kgs : 60+1ml/kg/hr

Extubation

After surgery, patients was positioned on his or her lateral side. After oropharynx was gently suctioned, the tracheal tube cuff was deflated. Once spontaneous respiratory pattern was confirmed by ETCO₂ monitoring, the endotracheal tube was removed gently and quickly oxygen (6L/min) was administered via a facemask immediately after extubation.

Complications associated with anaesthetic technique

Post operative nausea and vomiting

Respiratory depression

Post operative hypoxaemia

Emergence delirium

Sore throat

Post extubation croup

Post operative pulmonary oedema

Hepatic dysfunction

CONGENITAL SYNDROMES ASSOCIATED WITH DEAF MUTISM AND ANESTHETIC IMPLICATIONS

Treacher Collins syndrome - associated with facial dysplasia can lead difficult airway management.

Klippel Feil anomaly - restricted neck movement and difficult intubation.

Pendred syndrome - goitre and hypothyroidism

Jervell and Lange Nielsen syndrome - prolonged QT interval, ventricular arrhythmia

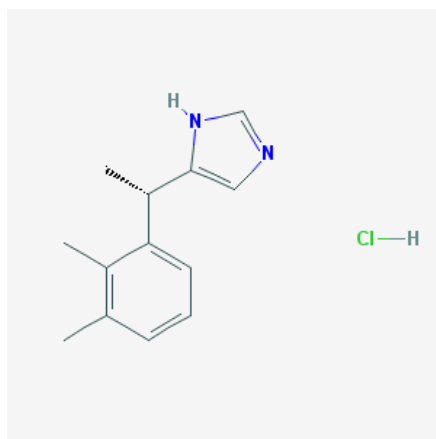
Usher syndrome - Impaired vision because of congenital cataract

Alport syndrome - associated with endocrine abnormalities and renal failure

PHARMACOLOGY OF DEXMEDETOMIDINE

Highly selective α_2 adrenergic agonist which produces sedation hypnosis and analgesia.

STRUCTURE OF DEXMEDETOMIDINE



Chemistry

4-(S)-alpha 2,3- Trimethylbenzyl) imidazole
Dexmedetomidine Hydrochloride is the S-enantiomer of medetomidine.

Chemically described as (+)- 4- (S)- [1- (2,3-dimethylphenyl) ethyl]-1H- imidazolemono hydrochloride.

Molecular weight: 236.74

Molecular formula: C₁₃H₁₆N₂HCl

Pharmacological Profile

Highly selective α_2 adrenergic agonist which shows a high ratio of specificity for the α_2 receptor. Dexmedetomidine belongs to the imidazole subclass of α_2 agonist. It is highly water soluble and is available as a preservative free and parenteral formulation.

Pharmacokinetics

T $\frac{1}{2}$ -6 minutes. It is 94% protein bound.

METABOLISM

Dexmedetomidine undergoes biotransformation by conjugation (41%) N-methylation (21%) or hydroxylation followed by conjugation in liver. The inactive metabolites are excreted in urine and feces. The elimination half life of Dexmedetomidine is two (2) to three (3) hours. Pharmacokinetics are similar in young adults and elderly.

MECHANISM OF ACTION

Dexmedetomidine is a highly selective α_2 agonist. 3 types of α_2 adreno receptors in humans are α_2A , α_2B , α_2C . The α_2A adrenoreceptor are located in the periphery where as α_2B and α_2C receptors are located in the brain and spinal cord. Presynaptic activation of α_2 adrenoreceptors inhibits the release of nor epinephrine and postsynaptic activation inhibits sympathetic activity and decreases blood pressure and heart rate producing sedation and anxiolysis.

Binding of Dexmedetomidine to α_2 adrenergic receptors in the spinal cord produces analgesia.

Action of Dexmedetomidine on α_2 receptors in the locus ceruleus produces sedation and hypnosis and action on α_2 receptors with in the locus ceruleus and with in the spinal cord produces analgesic effect.

ACTIONS

Effects on the central nervous system

SEDATION

The α_2 agonist exert their sedative effect by acting on the endogenous sleep-promoting pathways.

Although it produces good sedative effect, patient can be arousable alert and able to respond without any discomfort. It produces limited respiratory depression.

ANALGESIA

The primary site of action is thought to be spinal cord when injected through the intrathecal or epidural route. Systemic use of Dexmedetomidine shows narcotic sparing. The requirement of narcotics were reduced by 50% in patient, receiving Dexmedetomidine.

EFFECTS ON THE RESPIRATORY SYSTEM

The concentrations of Dexmedetomidine which produces sedation reduces minute ventilation but retains hyper capnic ventilation response.

EFFECTS ON THE CARDIOVASCULAR SYSTEM

Effects on the cardiovascular system produces decreased heart rate, decreased systemic vascular resistance and thereby decreases myocardial contractility and systemic Blood Pressure. Dexmedetomidine produces an initial increase in Blood pressure which occur 5 mins after administration due to the vasoconstrictive effects on peripheral receptors followed by decreased in Blood Pressure due to action on central α_2 adrenoreceptor activity. Administration of loading dose of Dexmedetomidine increases the incidence of hypotension and bradycardia. So avoiding the loading dose upto 0.4mcg/kg reduces the incidence of Hypotension.

DOSAGE AND ADMINISTRATION

Dexmedetomidine is supplied in 1 ml ampoule 50mcg/ml and 2ml ampoule 100mcg/ml.

Loading dose-0.5-1.0mcg/kg over 10min

Maintenance dose -0.3-0.7mcg/kg/hr.

USES

1. INTENSIVE CARE UNIT:

Dose requirement for opioids get reduced by >50% when compared with propofol or benzodiazepines in patients receiving Dexmedetomidine.

Dexmedetomidine produces adequate sedation with minimal respiratory depression.

Dexmedetomidine also used in the treatment of alcohol withdrawal and withdrawal of narcotics, benzodiazepines and recreational drugs.

2.ANAESTHESIA

- Dexmedetomidine attenuates the hemodynamic response to intubation when given 10-15 minutes before induction in the dose of 0.3-0.67mcg/kg.
- Used for securing the airway during fiberoptic intubation.
- As an anaesthetic adjuvant in sleep apnea patients, bariatric surgery, CABG surgery, vascular surgery, evoked potential study, thoracic surgery.

CONTRAINDICATIONS

Infusion over 24 hours.

In caesarean deliveries.

In patients with ejection fraction <30%.

Patients with preexisting bradycardia and bradyarrhythmias.

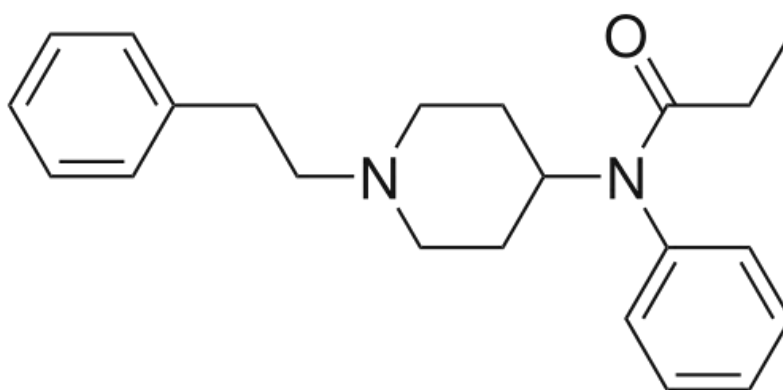
Hypotensive or hypovolemic patients.

Patients with raised intracranial tension.

PHARMACOLOGY OF FENTANYL

Fentanyl is a potent lipophilic synthetic opioid. Fentanyl is a μ receptor agonist with a short onset time and moderate duration of action. Sufentanyl and alfentanyl are derived from the Fentanyl citrate which is the synthetic parent opioid.

CHEMISTRY



N-Phenyl-N-[1(2-phenylethyl)-4Piperidinyl] Propanamide citrate.

The Phenylpiperidine (synthetic) opioid

Fentanyl skeleton structure

Molecular weight (free base) - 528.5 (336.5)

Pka (amino)- 8.43

SOLUBILITY

In alcohol	-	1 in 140
In water	-	1 in 40
Octanol/ Water partition coefficient	-	955

Fentanyl, μ agonist which has a more rapid onset and shorter duration of action than morphine. It has the greater lipid solubility compared with that of morphine.

Fentanyl produces dose related analgesia. Fentanyl in the dose of 0.5-3mcg/kg used as a supplement in spontaneously breathing anaesthetized patients. Fentanyl 5mcg/kg will suppress somatic and autonomic responses to surgical stimulation in ventilated patients. Fentanyl in the doses of 50mcg/kg may be used to induce and maintain anaesthesia.

Fentanyl reduces brain stem respiratory responsiveness to Co_2 as it is a potent respiratory depressant. Fentanyl has little effects on the circulation. It produces vagally mediated bradycardia and slight fall in systemic vascular resistance. The effect of skeletal muscle rigidity and clonic movements which

binder mechanical ventilation is reversed by naloxone and overcome by neuromuscular blocking drugs.

Fentanyl causes reduction in metabolic activity and oxygen consumption. Nausea and vomiting may be produced. Itching of the nose, cough suppression, pupillary constriction may also occur. Fentanyl may increase intracranial pressure in patients with severe head injury. It lowers the cerebral perfusion pressure. Fentanyl will reduce intra ocular pressure.

Relative contraindications for Fentanyl are

1. Raised ICP
2. Hypovolemia
3. Respiratory inadequacy

Pharmacokinetics

There are three- compartment model used to describe decay of plasma fentanyl concentration. Approximately 75 percent of an injected dose of Fentanyl was taken up by the lungs for first pass metabolism.

Volume of distribution ($3-6\text{Lkg}^{-1}$) and clearance ($10-20\text{ml Kg}^{-1}\text{min}^{-1}$) are high for fentanyl.

Approximately 80% of fentanyl which is bound to plasma proteins are taken up by the red blood cells (40%). It exists in the ionized form (>90%) as the pka of fentanyl is high (8.4) at physiological pH. Fentanyl has high lipid solubility and large volume of distribution. The tissue/ blood partition coefficient of fentanyl is 2-30 fold higher than alfentanyl. It gets metabolized in the liver. Because of its wide distribution in body tissues, Fentanyl is relatively long acting.

Fentanyl gets metabolized in the liver by β -dealkylation and hydroxylation. Because of high hepatic clearance and high hepatic extraction ratio, metabolism starts by 1.5 min after injection. Norfentanyl, the primary metabolite, is detectable in urine for upto 48 hours after IV fentanyl. Little fentanyl is excreted in the urine unchanged.

FACTORS WHICH ALTER PHARMACOKINETICS AND PHARMACODYNAMICS

- **Age:** In neonates, the elimination of fentanyl takes long period, pharmacokinetics which changes with advanced age, may play a minor role.

- **Weight:** pharmacokinetics does not change in lean and obese patients.

Renal failure: The clinical importance of kidney failure is less marked.

- **Hepatic failure:** Decrease in the fentanyl plasma concentration will be delayed in the hepatic failure.

REVIEW OF LITERATURE

*1. Mohamed Hafez El Saied et al*⁶ (Egyptian Journal of Anaesthesia 2015 vol 32 p55-59) studied the Anesthesia for cochlear implantation in pediatrics mandates deliberate hypotension to provide a better surgical field. Dexmedetomidine is α_2 adrenoceptor agonist that provides adequate sedation with high cardiovascular stability. We aimed to compare it with fentanyl as an anesthetic adjuvant. 52 pediatric patients (ASA I or II), undergoing cochlear implantation were randomized into dexmedetomidine (D) group and fentanyl (F) group (n = 26 for each). Anesthesia was induced by I.V. dexmedetomidine in (D) group at a bolus dose of 0.4 $\mu\text{g/kg}$ slowly infused over 10 min, then continuous infusion by a rate of 0.4 $\mu\text{g/kg/h}$ until the end of surgery. In (F) group; anesthesia was induced by I.V. fentanyl at a dose of 1 $\mu\text{g/kg}$ over 10 min, then continuous infusion by a rate of 1 $\mu\text{g/kg/h}$. This is followed by I.V. propofol and atracurium for both groups. Maintenance was done without additional muscle relaxant to allow monitoring of the facial nerve. Both groups were compared as regards the quality of the surgical field, intraoperative hemodynamics, recovery and discharge time, postoperative pain using objective pain score and the need for rescue analgesics and anti-

emetics in postanesthesia care unit (PACU). Dexmedetomidine group showed a decreased heart rate and mean arterial pressure than fentanyl group. These parameters were significantly decreased compared to the baseline throughout the procedure in D group. The quality of the surgical field was significantly better in D group than in F group. Postoperative pain and complications were not different between the two groups. Recovery and discharge time was significantly shorter for the patients in D group than in F group ($p < 0.05$). Dexmedetomidine infusion in cochlear implantation in pediatric patients was better in inducing deliberate hypotension and providing better quality scale of surgical field compared to fentanyl infusion. It allowed rapid recovery from anesthesia and reduced need for pain medication in the PACU.

2.Gupta N, et al¹⁰. (J Neurosurg Anesthesiol. 2013.) conducted study in Thirty-six children with spinal dysraphism at lumbosacral area, aged 8 to 12 years, undergoing corrective surgery were randomized to receive either dexmedetomidine or volume-matched saline (placebo) after positioned prone until beginning of skin closure. Inspired concentration of sevoflurane was changed to keep the bispectral index score between 45 and 55. Perioperative hemodynamics, intraoperative fentanyl and sevoflurane

consumption, and postoperative recovery profile and fentanyl consumption was observed by blinded observers. Postoperative pain, emergence agitation (EA), and discharge readiness from postanesthesia care unit was evaluated using the modified objective pain score, agitation Cole score, and modified Aldrete score, respectively. Fentanyl 0.5-1 µg/kg was administered for pain (objective pain score ≥ 4) or severe EA (agitation Cole score ≥ 4) lasting for >5 minutes. The 2 groups did not differ significantly with respect to demographics, duration of anesthesia, emergence, and extubation times. The intraoperative consumption of sevoflurane and fentanyl was significantly less in dexmedetomidine group (0.2 ± 0.1 vs. 0.3 ± 0.1 mL/min, $P < 0.0001$ and 2.3 ± 0.5 vs. 3.1 ± 0.6 µg/kg, $P = 0.0001$, respectively), along with a lower mean heart rate ($P < 0.001$). The mean systolic blood pressure ($P = 0.98$) and incidence of bradycardia and hypotension was comparable in between the 2 groups. Postoperatively, the children in dexmedetomidine group had significantly lower pain scores ($P < 0.0001$), agitation scores ($P < 0.0001$), and time to achieve full modified Aldrete score [0 (0 to 10) vs. 10 (0 to 20) min, $P = 0.001$]. The postoperative consumption of fentanyl was significantly less in dexmedetomidine group [0 (0 to 1.04) vs. 0.88 (0 to 3) µg/kg,

P=0.003], along with a longer time of first analgesic requirement [600 (5 to 2100) vs. 5 (5 to 185) min, P=0.0001]. The mean heart rate and systolic blood pressure were higher in placebo group (P<0.001), whereas no difference was observed in respiratory rate (P=0.73) and arterial oxygen saturation (P=0.36). The number of patients with postoperative nausea and vomiting was significantly lower in dexmedetomidine group [2 (11.1%) vs. 9 (50%), P=0.03]. Intraoperative use of dexmedetomidine in children undergoing spinal surgery results in a favorable recovery profile with reduced postoperative pain and EA, without adverse perioperative hemodynamic effects.

3.Goyal S, et al⁹ (Anesth Essays Res. 2017 Jul-Sep.) conducted the study to compare the efficacy of dexmedetomidine with fentanyl in breast cancer surgery in terms of haemodynamic stability, anaesthetic sparing effects, recovery profile and postoperative analgesia. randomized prospective controlled trial, a total of 60 female patients were randomly assigned into two groups. Patients in group F (n = 30) received a loading dose of fentanyl 2 µg/kg with maintenance dose of 0.5 µg/kg/h and in group D (n = 30) received dexmedetomidine 1 µg/kg as loading dose with maintenance dose of 0.25 µg/kg/h till the end of surgery.

Hemodynamic parameters, desflurane requirement, recovery profile and postoperative analgesia were monitored and compared in both the groups. Mean HR was less in group D compared to group F intraoperatively, before and after extubation with a significant p value. The mean MAP was also lower in group D compared to group F at all the time points. MAC requirements were found lower in group D compared to group F with a significant $P < 0.001$. Cognitive recovery in the form of time to respond to verbal commands, time to extubation, time to orientation was early in dexmedetomidine group. Dexmedetomidine can be used as suitable alternative to fentanyl in breast cancer surgeries due to better hemodynamic stability, anaesthetic sparing effects and better recovery profile.

4.Passaint Fahim Hassan, Amany Hassan Saleh et al 7

(Anesthesia Essays and Researches) aimed to compare both dexmedetomidine and magnesium sulfate as regards their efficacy in inducing deliberate hypotension and providing better quality of the surgical field during cochlear implantation in pediatrics. Prospective, randomized double-blinded study. Forty-six pediatric patients aging 1.5–2.5 years of either sex with American Society of Anesthesiologists physical status classes I and II were

randomized into dexmedetomidine (D) group (n = 23) and magnesium sulfate (M) group (n = 23). In the D group, after induction of anesthesia but before the surgery, a bolus dose of 0.4 µg/kg slowly infused over 10 min, then continuous infusion by a rate of 0.4 µg/kg/h until the end of surgery. In M group, after induction of anesthesia but before the surgery, magnesium sulfate 10% (50 mg/kg) was given slowly, then continuous infusion by a rate of 10 mg/kg/h during the whole surgery. Intraoperative hemodynamics, quality of surgical field, fentanyl consumption, blood loss, operative time, FLACC pain scores, and adverse effects were compared in both groups. Surgical field score and blood loss were better in D group than M group. Fentanyl consumption was less in D group than M group. Heart rate and mean atrial blood pressure were lower in D group except in the initial times than M group. In our study, both drugs were effective in achieving hypotensive anesthesia in pediatrics; however, dexmedetomidine proved to have superior effect on the surgical field and blood loss compared to magnesium sulfate with no intra- and post-operative complications for cochlear implantation surgery.

5.Aynur Akin,Adnan Bayram, Aliye Esmaoglu⁴ (Pediatric Anesthesia Volume 22,p 871–876)conducted the study of

Dexmedetomidine vs midazolam for premedication of pediatric patients undergoing anesthesia. Dexmedetomidine, an α_2 -receptor agonist, provides sedation, analgesia, and anxiolytic effects, and these properties make it a potentially useful anesthetic premedication. In this study, we compared the effects of intranasal dexmedetomidine and midazolam on mask Ninety induction and preoperative sedation in pediatric patients. children classified as ASA physical status I, aged between 2 and 9, who were scheduled to undergo an elective adenotonsillectomy, were enrolled for a prospective, randomized, and double-blind controlled trial. All of the children received intranasal medication approximately 45–60 min before the induction of anesthesia. Group M ($n = 45$) received $0.2 \text{ mg} \cdot \text{kg}^{-1}$ of intranasal midazolam, and Group D ($n = 45$) received $1 \text{ } \mu\text{g} \cdot \text{kg}^{-1}$ of intranasal dexmedetomidine. All of the patients were anesthetized with nitrous oxide, oxygen, and sevoflurane, administered via a face mask. The primary end point was satisfactory mask induction, and the secondary end points included satisfactory sedation upon separation from parents, hemodynamic change, postoperative analgesia, and agitation score at emergence. Satisfactory mask induction was achieved by 82.2% of Group M and 60% of Group D ($P = 0.01$). There was no evidence

of a difference between the groups in either sedation score ($P = 0.36$) or anxiety score ($P = 0.56$) upon separation from parents. The number of patients who required postoperative analgesia was higher in Intranasal dexmedetomidine and the midazolam group ($P = 0.045$). midazolam are equally effective in decreasing anxiety upon separation from parents; however, midazolam is superior in providing satisfactory conditions during mask induction

6.Hwang W, Lee J, Park J, Joo J et al¹ (BMC Anesthesiol. 2015 Feb 24;15:21) studied the effect of Dexmedetomidine versus remifentanyl in postoperative pain control after spinal surgery.TotalTotalTotalTotalTotal intravenous anesthesia (TIVA) is used widely in spinal surgery because inhalational anesthetics are known to decrease the amplitude of motor evoked potentials. Presently, dexmedetomidine is used as an adjuvant for propofol-based TIVA. We compared the effects of remifentanyl and dexmedetomidine on pain intensity as well as the analgesic requirements after post-anesthesia care unit (PACU) discharge in patients undergoing spinal surgery.Forty patients scheduled for posterior lumbar interbody fusion (PLIF) surgery under general anesthesia were enrolled. Anesthesia was maintained using propofol at 3-12 mg/kg/h and remifentanyl at 0.01-0.2

$\mu\text{g/kg/min}$ in Remifentanyl group or dexmedetomidine at 0.01-0.02 $\mu\text{g/kg/min}$ in Dexmedetomidine group, keeping the bispectral index between 40 and 60. Patient-controlled analgesia (PCA) made of hydromorphone was applied once the patients opened their eyes in the PACU. The visual analog scale (VAS) score, PCA dosage administered, and postoperative nausea and vomiting (PONV) were recorded at the time of discharge from the PACU (T1) and at 2 (T2), 8 (T3), 24 (T4), and 48 hours (T5) after surgery. The VAS score in Remifentanyl group was significantly higher than that in Dexmedetomidine group at immediate and late postoperative period (4.1 ± 2.0 vs. 2.3 ± 2.2 at T1, and 4.0 ± 2.2 vs. 2.6 ± 1.7 at T5; $P < 0.05$). Dexmedetomidine group had a statistically significantly lower PCA requirement at every time point after surgery except directly before discharge from the PACU (3.0 ± 1.2 ml vs. 2.3 ± 1.4 ml at T1; $P > 0.05$, but 69.7 ± 21.4 ml vs. 52.8 ± 10.8 ml at T5; $P < 0.05$). Patients in Remifentanyl group displayed more PONV until 24 hours post-surgery. Dexmedetomidine displayed superior efficacy in alleviating pain and in postoperative pain management for 48 hours after PLIF. Therefore, dexmedetomidine may be used instead of remifentanyl as an adjuvant in propofol-based TIVA.

7.*Dr. Marcia L. Buck, Douglas F. Willson et al*² (vol 28,p51-57)conducted study to determine the safety, effectiveness, and dosing of dexmedetomidine in intensive care infants and children who require sedation, and the rationale for patient selection. Eleven-bed pediatric intensive care unit in a university-affiliated children's hospital. Seventeen infants and children who received dexmedetomidine .Data were collected on demographics, blood pressure and heart rate measurements, and adverse effects. The rationale for dexmedetomidine use, its dosing, use of other sedatives, and treatment duration were also recorded. Twenty treatment courses in 17 patients (median age 5 mo, range 1 mo-17 yrs) were evaluated. Ten patients (59%) had chronic neurologic impairments (including Down syndrome in nine [53%]). Thirteen (76%) had undergone cardiac surgery, two (12%) had respiratory failure, one (6%) had endocarditis, and one (6%) had undergone scoliosis repair. In 15 (75%) of 20 cases, dexmedetomidine was started to minimize the use of midazolam before extubation; in 13 (87%) of these cases, the patients were extubated within 24 hours. The remaining patients could not tolerate midazolam, and dexmedetomidine was used as an alternative. No loading doses were given. The mean \pm SD starting dose was 0.2 ± 0.2 $\mu\text{g/kg/hour}$,

with a maximum of $0.5 \pm 0.2 \mu\text{g/kg/hour}$. Mean \pm SD duration was 32 ± 21 hours (range 3–75 hrs); 10 courses exceeded 24 hours. Mean arterial pressures before and after starting treatment were not significantly different ($p=0.76$), nor were values at discontinuation ($p=0.31$) or 12 hours later ($p=0.29$). No significant differences were noted in heart rate at the start ($p=0.09$), at discontinuation ($p=0.06$), or 12 hours later ($p=0.17$). One patient (6%) developed hypotension; no other adverse effects were noted. With careful patient selection and a conservative approach to dosing, dexmedetomidine was a useful sedative in children requiring mechanical ventilation. It allowed for a reduction or elimination of other sedatives, and it was particularly useful in children with chronic neurologic impairments. Dexmedetomidine was well tolerated, with no clinically significant effects on blood pressure or heart rate.

8. Sabry Mohamed Amin et al Mohamed Gamal Eldin Elmawy et al⁵ (Egyptian Journal of Anaesthesia 2016 vol 32 p255-261) conducted the study to determine the efficacy of dexmedetomidine versus esmolol usage as an adjunct to induce controlled hypotension in children undergoing cochlear implant surgery. 70 children aged 2–4 years scheduled for cochlear implant

surgery under general anesthesia. Patients were randomly allocated according to drugs used into two equal groups (35 patients in each group). Interventions: Group (D): The patients in this group received a bolus dose of dexmedetomidine 0.5 ug/kg over 10 min followed by continuous infusion 0.2–0.5 ug/kg/h after induction of anesthesia but before surgery. Group (E): The patients in this group received a bolus dose of esmolol 0.5 mg/kg over 10 min followed by continuous infusion 100–300 ug/kg/min after induction of anesthesia but before surgery. The quality of surgical field was comparable between both groups in all times of measurements. The time to first analgesic request was statistically significant longer in group (D) than in group (E) and the total tramadol consumption was statistically significant less in group (D) than in group (E). In our study both dexmedetomidine and esmolol were effective in reducing MABP, and lowering the heart rate providing dry surgical field and ensured good surgical condition during cochlear implant surgery in pediatric patients.

9. Goksu S, Arik H, Demiryurek S et al⁸ (Eur J Anaesthesiol 2008;25(1):22-8) conducted the study to investigate the haemodynamic effects of perioperatively administered dexmedetomidine, a new generation alpha-2-agonist, in patients for

functional endoscopic sinus surgery. Sixty-two patients who were planned to undergo functional endoscopic sinus surgery under local anaesthesia were included in the study. Following meperidine premedication, both groups were monitored in a standard manner with electrocardiogram, non-invasive blood pressure and percentages of peripheral saturation of oxygen. Saline intravenous infusion was started in the placebo group, and dexmedetomidine bolus intravenous infusion (an initial loading dose of 1 microg kg⁻¹ given for a 10-min period followed by 0.7 microg kg⁻¹ h⁻¹) was administered to the treatment group. Maintenance dose infusion was stopped 15 min before the end of the surgical procedure. Systolic, diastolic and mean arterial pressures, and heart rate markedly decreased in the dexmedetomidine group. However, dexmedetomidine had no effect on serum nitric oxide levels, measured by a nitric oxide/ozone chemiluminescence method. No significant difference was found in oxygen saturation levels of the two groups. Postoperative nausea and vomiting rates were significantly lower in the dexmedetomidine group. No adverse effects were observed with this alpha-2-agonist. Dexmedetomidine provided appropriate levels of sedation.

10.Jana JJ, Vaid N, Shanbhag J. (Cochlear Implants Int 2013 Jun;14(3): 169-73) conducted the study to evaluate the effects of intravenous anaesthesia on intraoperative monitoring of cochlear implant function in paediatric cochlear implantees. study conducted in 29 children. Age - 18 months to 11 yrs. All children had bilateral severe to profound sensorineural hearing loss. Children with compromised neural/cochlear anatomy were excluded. Patients were maintained on an infusion of Fentanyl @ 0.3-0.6 ug/kg/hr and Propofol @ 4-8 mg/kg/hr intraoperatively. Intraoperative measurements were done after performing the train of four test on the adductor pollicis muscle Results It was observed that ESRT was unaffected by intravenous anaesthesia. Electrical impedance and ECAP were not affected by any technique of anaesthesia. Intravenous anaesthesia has little or no effect on the intraoperative auditory thresholds and is therefore recommended for determining these thresholds during cochlear implant surgery.

11.Joseph S. Yeh, Kimberly L. Mooney, Kevin Gingrich
(pediatric ears vol 121,P 2240-2244)
Investigated the incidence of anesthetic complications in young patients undergoing general anesthesia for CI.
A retrospective chart review of 123 patients younger than 18 years,

who underwent CI was conducted for identification of intra- and postoperative anesthesia-related complications. Of the 123 CI procedures, eight patients had nine anesthesia-related complications, yielding a complication rate of 6.5% and included the following: postoperative wheezing/stridor (5 cases), laryngospasm (3 cases), and emesis during inhalational induction (1 case). Divided by age group, 12 patients were <12 months with one complication (8%), 18 patients were between 1 and 2 years with one complication (5.6%), 35 patients were between 2 and 5 years with one complication (3%), 39 patients were between 5 and 12 years with five complications (13%), and 19 patients were older than 12 years with no complication (0%). Logistic regression failed to identify a significant association of any collected variable(s) with the observed complications. The incidence of complications is similar to that previously reported in elderly patients (4.3%) (Pearson χ^2 , $P = .523$). General anesthesia is well tolerated by pediatric patients undergoing CI, even under 1 year of age. Significant perioperative complications are primarily respiratory, are usually free of long-term sequelae, and occur with an incidence similar to other reported age groups.

MATERIALS AND METHODS

This study was conducted at the Institute of Otorhinolaryngology, Rajiv Gandhi Government General Hospital, Madras Medical College, Chennai-3 between March 2017- August 2017 on 40 patients of ASA physical status I and II undergoing elective cochlear implantation under general anaesthesia. This study was done after Government General Hospital Ethical committee approval and a written informed consent obtained from all the patients parent/guardian included in this study.

STUDY DESIGN

This study was done in a prospective double blinded randomized manner. Each group consisted of twenty patients.

Group-D

Patients in this group received loading dose of Dexmedetomidine 0.4mcg/kg and maintenance dose of Dexmedetomidine 0.4mcg/kg/hr through intravenous infusion.

Group-F

Patients in this group received loading dose of Fentanyl 1mcg/kg and maintenance dose of Fentanyl 1mcg/kg/hr through intravenous infusion.

In this study Dexmedetomidine hydrochloride 100mcg/1ml and preservative free fentanyl 50mcg/1ml. All solutions were prepared under strict aseptic precautions by the OT incharge anaesthesiologist uninvolved in the observation of results.

SELECTION OF CASES

Inclusion Criteria

- ❖ Age <6 years
- ❖ ASA physical status I and II
- ❖ Surgery: Elective Surgery
- ❖ Who have given valid informed consent

Exclusion Criteria

- ❖ Not satisfying inclusion criteria
- ❖ Patients with known allergy to Fentanyl or Dexmedetomidine
- ❖ Fever
- ❖ Upper respiratory tract infection
- ❖ Coagulopathy
- ❖ Prolonged QT interval
- ❖ Ventricular arrhythmia
- ❖ Congenital abnormalities.

PRE ANAESTHETIC EVALUATION

Patients included in this study underwent preoperative evaluation which included the following.

HISTORY

History of previous surgery, underlying medical illness and hospitalization.

PHYSICAL EXAMINATION

Vital Signs

Body weight

Examination of CVS, RS, CNS

Airway Assessment

INVESTIGATION

Haemoglobin (Hb), BT, CT, Renal Function Test (RFT), ECG, Chest X-Ray, Blood grouping and typing were done. Patient who satisfied the inclusion criteria were explained about the nature of the study and the anaesthetic procedures and written informed consent were obtained from all patients parent/ guardian included in the study.

SENSITIVITY TEST

Skin wheal sensitivity test was done for all patients half an hour before surgery. Pulse rate, BP, SPO₂ was recorded.

TECHNIQUE

In the OT equipment for airway management and emergency drugs were kept ready. Patient was shifted to OT. The patient was placed on the operating table after checking the horizontal position. ECG, NIBP, SPO₂ were connected to the patient. Preoperative baseline systolic and diastolic BP, HR, SPO₂ were recorded. Preoxygenation with 100% oxygen for 3mins was done. Premedication was done with Inj.Glycopyrrolate IV 0.01mg/kg and Inj.Dexamethasone IV 0.15mg/kg. The anaesthesiologist who were unaware of the drugs performed induction and made observations in all the patients involved in the study. This is followed by Inj.Propofol IV 2mg/kg and Inj.Atracurium IV 0.5mg/kg was done. After ventilation, direct laryngoscopy and endotracheal intubation was done in the sniffing position with appropriate size ETT and fixed after checking bilateral chest expansion and air entry. Anaesthesia was maintained using a mixture of N₂O and O₂ in the ratio of 2:2, 2% sevoflurane and through IV infusion maintenance

dose of test drug was started by the anesthesiologist unaware of it.
All the following parameters were observed.

VITAL SIGNS

The Systolic and diastolic BP, PR& SPO2 were recorded 1 minute after induction, 1 minute after intubation and thereby every 15 minutes throughout the intra operative period. The above vital signs at the completion of surgery were noted. Hypotension defined as fall in systolic BP >30% from baseline or MAP <60mm of Hg. This was managed with Inj.Ephedrine 6mg increment. Bradycardia was defined as heart rate <50/mt and this was managed with Inj.Atropine 0.01mg/kg IV. Blood loss more than the allowable loss was replaced with blood.

QUALITY OF THE SURGICAL FIELD

0 No Bleeding

1 Slight bleeding- Blood evacuation not necessary

2 Slight bleeding- sometimes blood has to be evacuated

3 Low bleeding- blood loss to be often evacuated operative field is visible for some seconds after evacuation.

4 Average bleeding- blood has to be often evacuated.
Operative field is visible only right after evacuation.

5 High bleeding- constant blood evacuation is needed.
Sometimes bleeding exceed evacuation. Surgery is hardly possible.

POST OPERATIVE ASSESSMENT

Post operative recovery time was assessed by modified Aldrete recovery score and assessment of post operative pain by FLACC behavioral pain assessment scale and need for post operative analgesia was assessed.

MODIFIED ALDRETE RECOVERY SCORE

<i>Variables</i>	<i>Evaluated</i>
<i>Activity</i>	
Able to move four extremities on command.	2
Able to move two extremities on command.	1
Able to move no extremities on command	0
<i>Breathing</i>	
Able to breathe deeply and cough freely	2
Dyspnea	1
Apnea	0
<i>Circulation</i>	
Systemic blood pressure $\leq 20\%$ of the Preanesthetic	2

<i>Variables</i>	<i>Evaluated</i>
level	
Systemic blood pressure is 20% to 50% Of the preanesthetic level	1
Systemic blood pressure $\geq 50\%$ of the Preanesthetic level	0
<i>Conciousness</i>	
Fully awake	2
Arousable	1
Not responding	0
<i>Oxygen saturation (pulse oximetry)</i>	
$>92\%$ while breathing room air	2
Needs supplemental oxygen to maintain saturation $>90\%$	1
$<90\%$ with supplemental oxygen	0

FLACC SCALE

FACE

Score 0 if the patient has a relaxed face,makes eye contact,shows interest in surroundings.

Score 1 if the patient has a worried facial expression,with eyebrows lowered, eyes partially closed, cheeks raised,mouth pursed.

Score 2 if the patient has deep furrows in the forehead, closed eyes, an open mouth, deep lines around nose and lips.

LEGS

Score 0 if the muscle tone and motion in the limbs are normal.

Score 1 if the patient has increased tone, rigidity or tension; if there is intermittent flexion or extension of the limbs.

Score 2 if the patient has hypertonicity, the legs are pulled tight, there is exaggerated flexion or extension of the limbs, tremors.

ACTIVITY

Score 0 if the patient moves easily and freely, normal activity or restrictions.

Score 1 if the patient shifts positions, appears hesitant to move, demonstrates guarding, a tense torso, pressure on a body part.

Score 2 if the patient is in a fixed position, rocking; demonstrates side to side head movement or rubbing of a body part.

CRY

Score 0 if the patient has no cry or moan, awake or asleep.

Score 1 if the patient has occasional moans, cries, whimpers, sighs.

Score 2 if the patient has frequent or continuous moans, cries, grunts.

CONSOLABILITY

Score 0 if the patient is calm and does not require consoling.

Score 1 if the patient responds to comfort by touching or talking in 30 seconds to 1 minute.

Score 2 if the patient requires constant comforting or is inconsolable.

INTERPRETING THE BEHAVIORAL SCORE

Each category is scored on the 0-2 scale, which results in a total score of 0-10.

0 = Relaxed and comfortable

1-3 = Mild discomfort

4-6 = Moderate pain

7-10 = severe discomfort or pain or both.

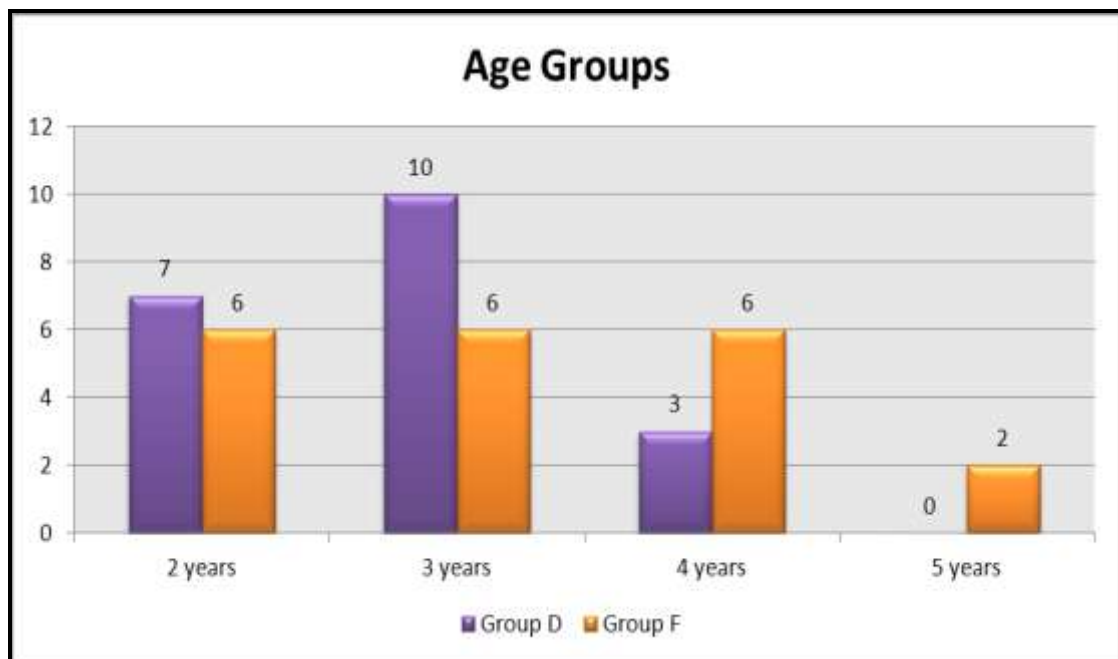
OBSERVATION AND RESULTS

This study was conducted at the Institute of Anaesthesiology and Critical care, Chennai. Forty(40) patients were included in this double blinded randomized controlled study. The patients were divided into two groups, group D and group F. Patients in group D received loading dose 0.4 mcg/kg and maintenance dose 0.4 mcg/kg/hr and patients in group F received loading dose 1 mcg/kg and maintenance dose 1 mcg/kg/hr through intravenous infusion.

STATISTICS

Descriptive statistics was done for all data and were reported in terms of mean values and percentages. Suitable statistical tests of comparison were done. Continuous variables were analysed with the unpaired t test.. Categorical variables were analysed with the Chi-Square Test and Fisher Exact Test. Statistical significance was taken as $P < 0.05$. The data was analysed using SPSS version 16 and Microsoft Excel 2007.

AGE

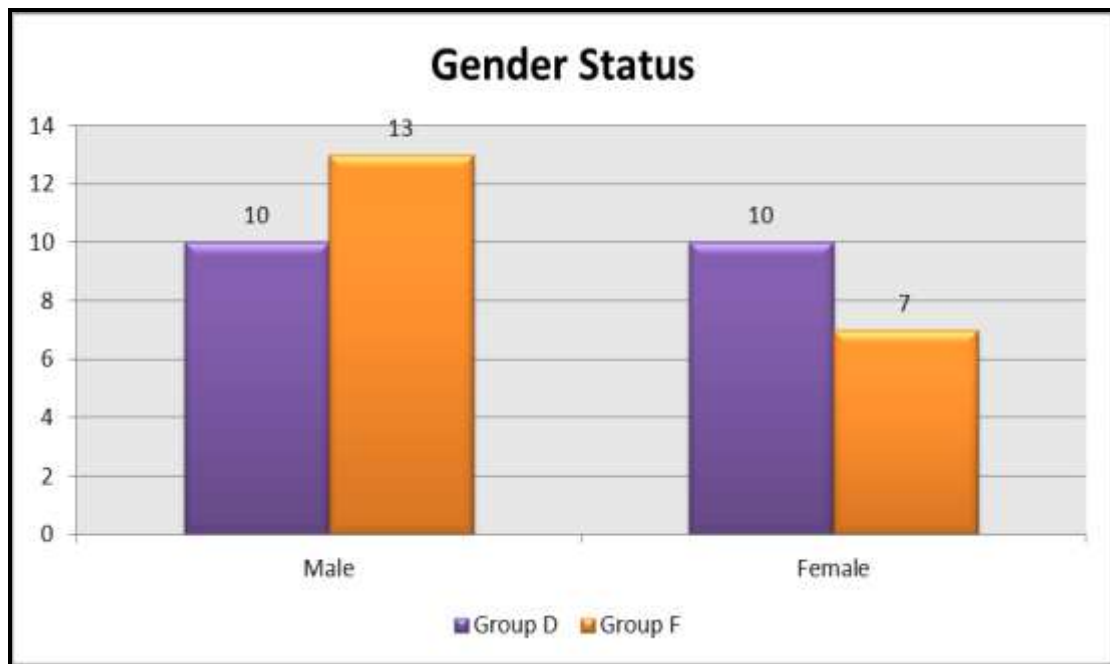


Age Groups	Group D	%	Group F	%
2 years	7	35.00	6	30.00
3 years	10	50.00	6	30.00
4 years	3	15.00	6	30.00
5 years	0	0.00	2	10.00
Total	20	100.00	20	100.00

Age Distribution	Group D	Group F
Mean	2.80	3.20
SD	0.70	1.01
P value Unpaired t Test		0.1516

It is evident from the age distribution table that most of the group dexmedetomidine subjects were 3 years old (50%) with a mean age of 2.80 years. Similarly in group fentanyl majority were in same age group (30%) with a mean age of 3.20 years. (p=0.1516). The data subjected to unpaired t test reveals the existence of statistically insignificant association between age distribution and intervention groups ($p > 0.05$)

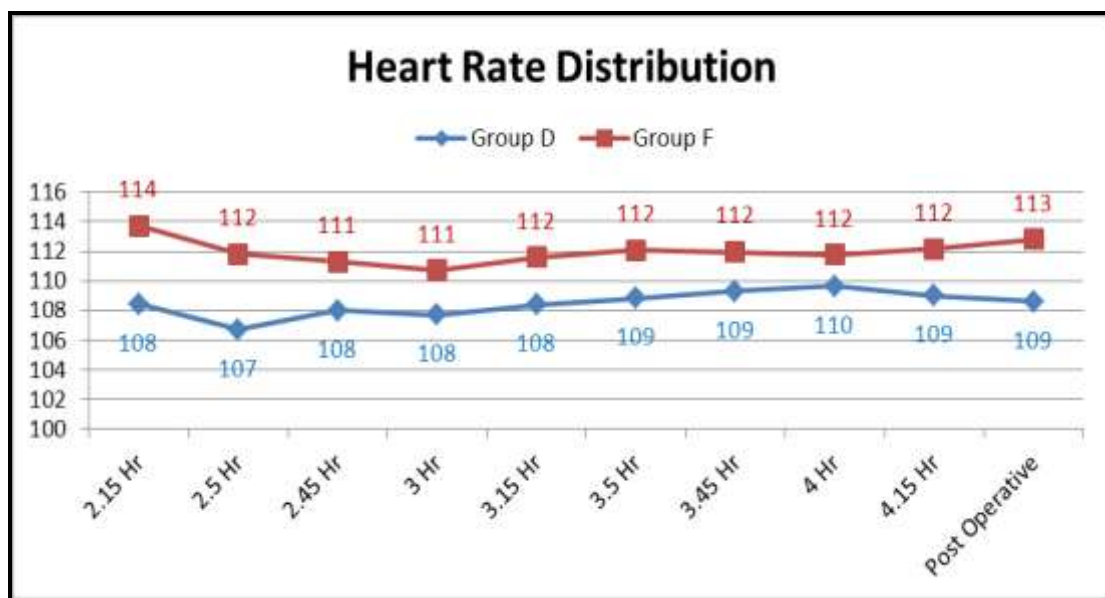
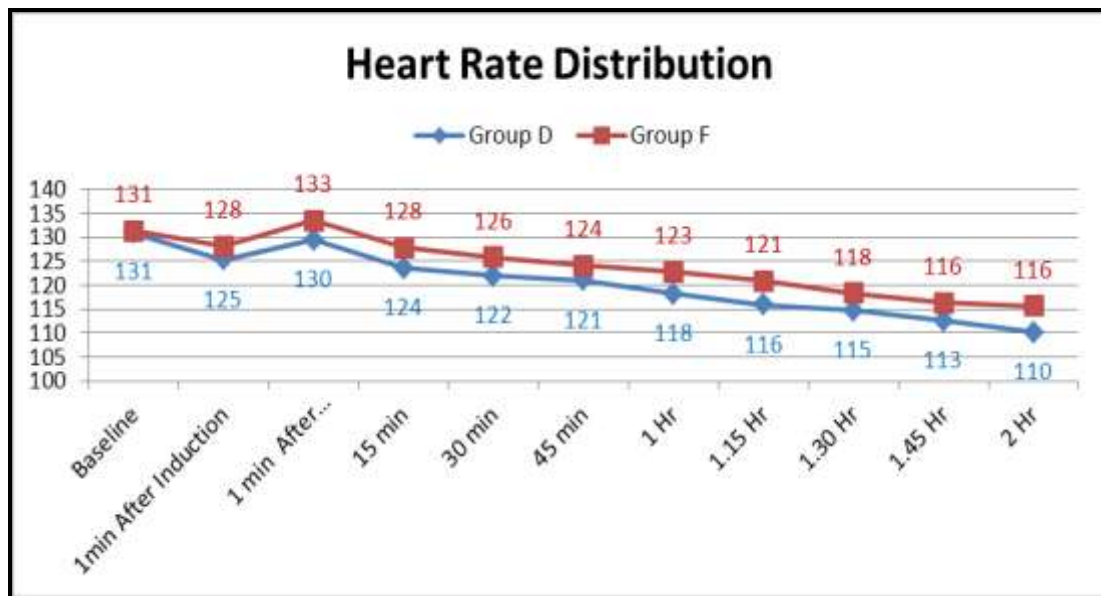
GENDER



Gender Status	Group D	%	Group F	%
Male	10	50.00	13	65.00
Female	10	50.00	7	35.00
Total	20	100.00	20	100.00
P value Fishers Exact Test			0.3617	

It is evident from the gender status table that most of the group dexmedetomidine subjects were males (50%) and in group fentanyl majority belonged to same gender (63%) ($p=0.3617$). The data subjected to fishers exact test reveals the existence of statistically insignificant association between gender status and intervention groups ($p > 0.05$)

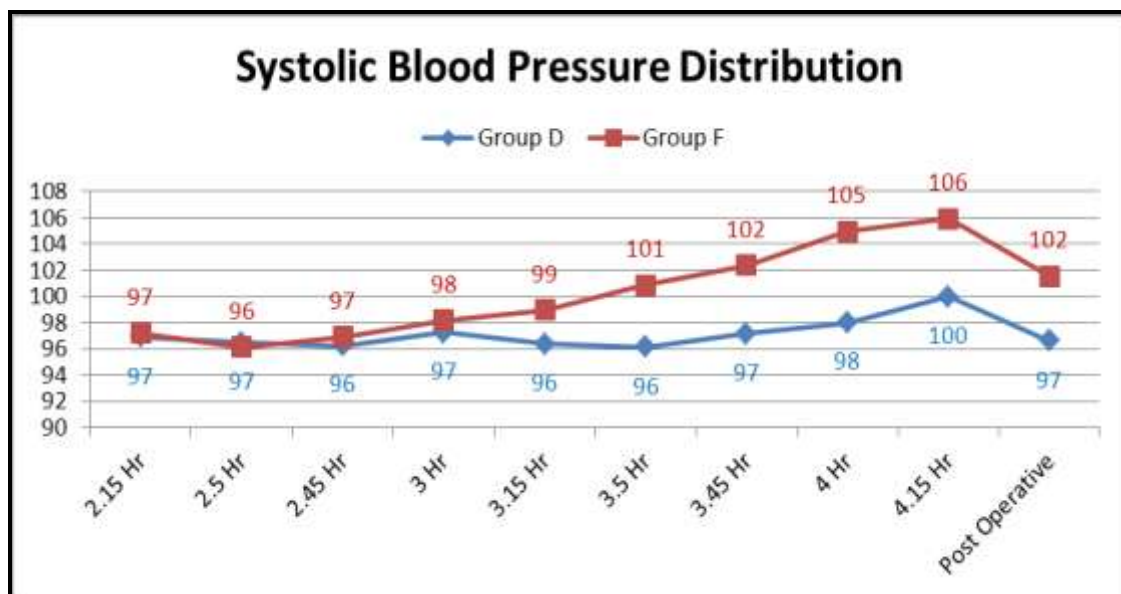
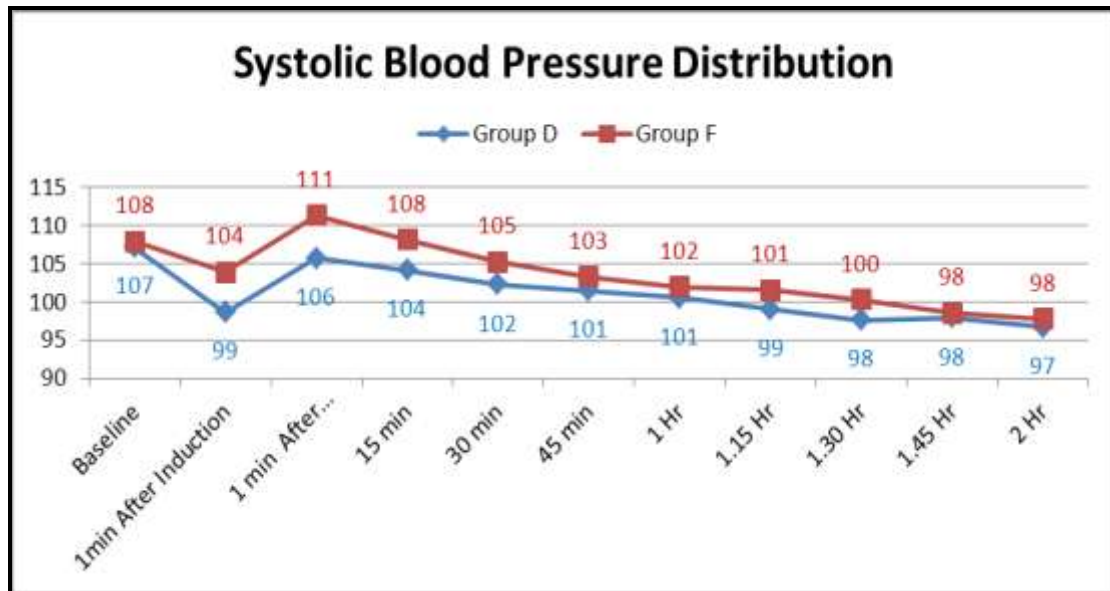
HR



Heart Rate Distribution	Group D		Group F		P value Unpaired t Test
	Mean	SD	Mean	SD	
Baseline	130.90	12.53	131.31	12.53	0.9465
1min After Induction	125.25	11.17	128.16	11.17	0.1771
1 min After Intubation	129.50	12.56	133.41	12.56	0.8468
15 min	123.60	8.59	127.81	8.59	0.8722
30 min	121.95	8.63	125.86	8.63	0.8304
45 min	120.95	10.17	124.06	10.17	0.8617
1 Hr	118.20	10.44	122.76	10.44	0.5486
1.15 Hr	115.85	11.60	120.81	11.60	0.4924
1.30 Hr	114.65	11.46	118.31	11.46	0.3355
1.45 Hr	112.60	10.78	116.31	10.78	0.2589
2 Hr	110.20	11.98	115.61	11.98	0.8602
2.15 Hr	108.45	11.33	113.71	11.33	0.8186
2.5 Hr	106.70	9.98	111.81	9.98	0.7148
2.45 Hr	108.00	9.72	111.31	9.72	0.3524
3 Hr	107.70	9.91	110.71	9.91	0.5463
3.15 Hr	108.40	10.55	111.60	10.55	0.3907
3.5 Hr	108.82	11.01	112.07	11.01	0.5797
3.45 Hr	109.29	8.46	111.96	8.46	0.6821
4 Hr	109.67	0.00	111.76	0.00	0.4438
4.15 Hr	100.00	0.00	112.16	0.00	0.7787
Post Operative	108.60	8.27	112.81	8.27	0.3159

It is evident from the heart rate distribution table that most of the group dexmedetomidine subjects had a mean overall heart rate of 114.87 beats per min. Similarly in group fentanyl majority had a mean overall heart rate of 117.65 beats per min. ($p=0.0674$). The data subjected to unpaired t test reveals the existence of statistically insignificant association between heart rate distribution and intervention groups ($p > 0.05$).

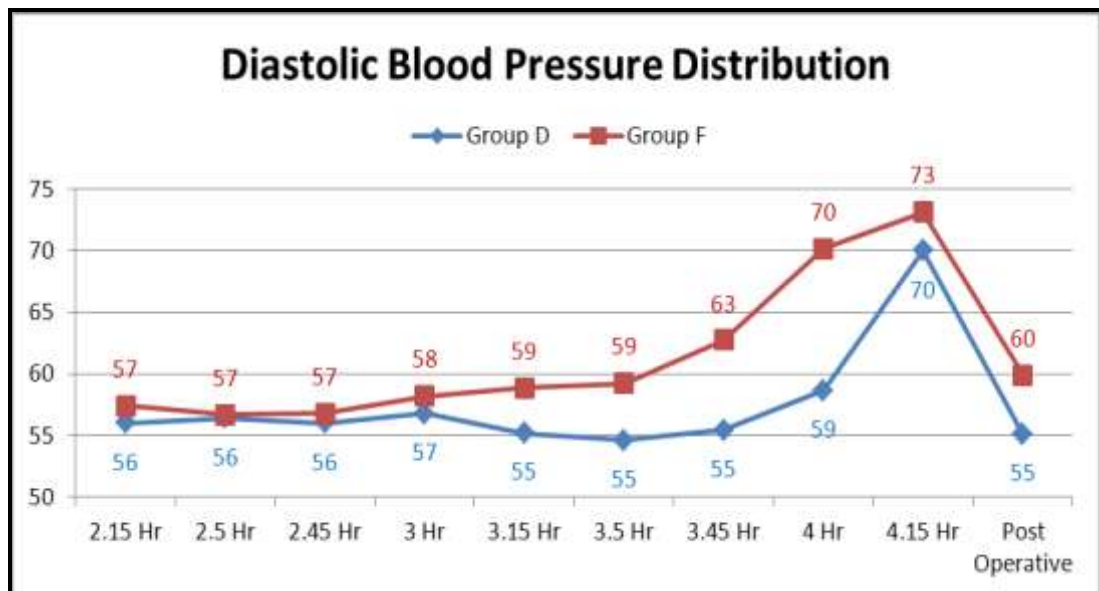
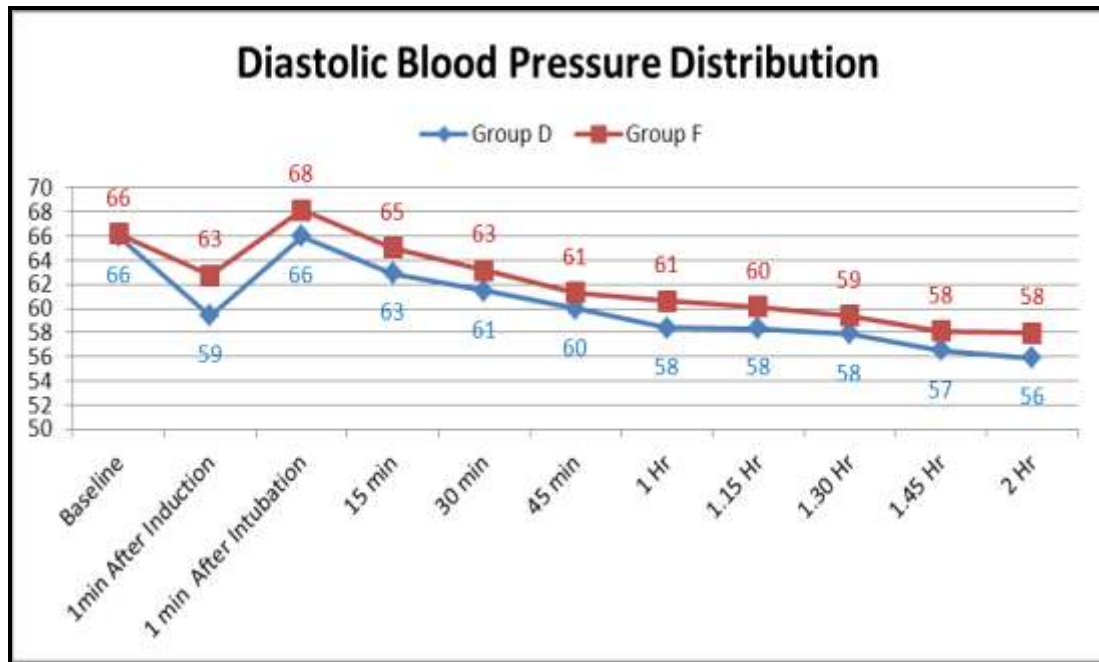
SBP



Systolic Blood Pressure Distribution	Group D		Group F		P value Unpaired t Test
	Mean	SD	Mean	SD	
Baseline	107.15	6.09	107.91	6.09	0.1404
1min After Induction	98.60	5.89	103.89	5.89	0.9271
1 min After Intubation	105.75	4.30	111.29	4.30	0.4171
15 min	104.15	5.34	108.14	5.34	0.5057
30 min	102.25	6.22	105.24	6.22	0.3491
45 min	101.45	5.61	103.29	5.61	0.3067
1 Hr	100.55	5.60	101.94	5.60	0.2206
1.15 Hr	99.00	7.33	101.49	7.33	0.1412
1.30 Hr	97.60	6.68	100.29	6.68	0.1468
1.45 Hr	97.90	5.67	98.49	5.67	0.2063
2 Hr	96.70	5.97	97.74	5.97	0.1361
2.15 Hr	96.90	6.71	97.19	6.71	0.1768
2.5 Hr	96.50	6.66	96.14	6.66	0.149
2.45 Hr	96.25	7.95	96.89	7.95	0.1447
3 Hr	97.25	6.75	98.19	6.75	0.1486
3.15 Hr	96.40	6.29	98.94	6.29	0.0132
3.5 Hr	96.12	7.56	100.85	7.56	0.0108
3.45 Hr	97.14	11.57	102.34	11.57	0.0982
4 Hr	98.00	0.00	104.94	0.00	>0.9999
4.15 Hr	100.00	0.00	105.94	0.00	>0.9999
Post Operative	96.60	7.96	101.54	7.96	0.1754

It is evident from the systolic blood pressure distribution table that most of the group dexmedetomidine subjects had a mean overall SBP of 98.76 mm Hg. Similarly in group fentanyl majority had a mean overall SBP of 101.66 mm Hg. ($p = 0.0756$). The data subjected to unpaired t test reveals the existence of statistically insignificant association between SBP distribution and intervention groups ($p > 0.05$).

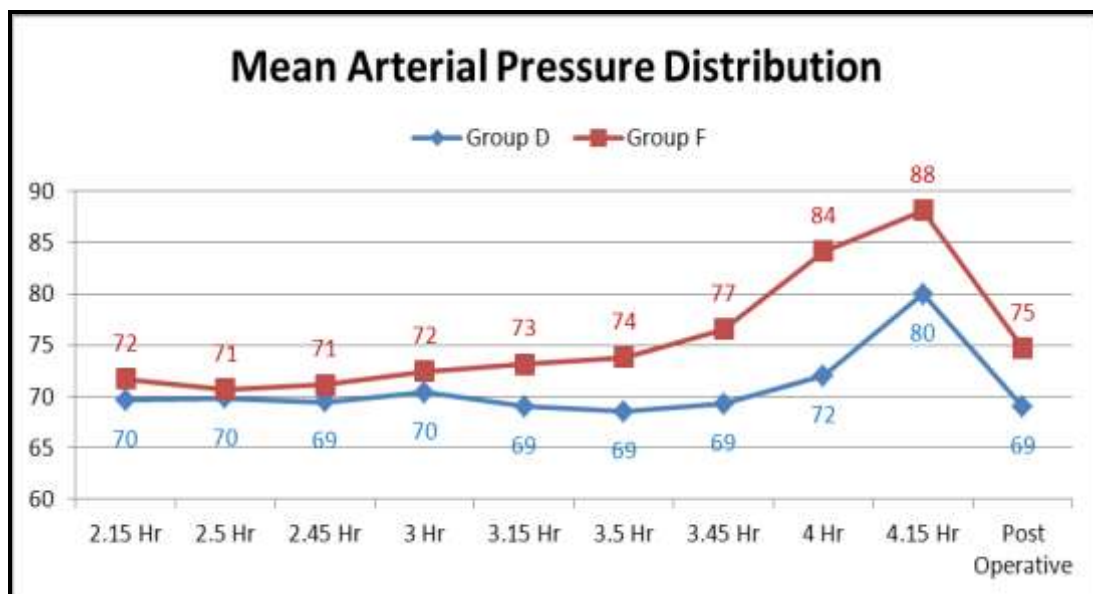
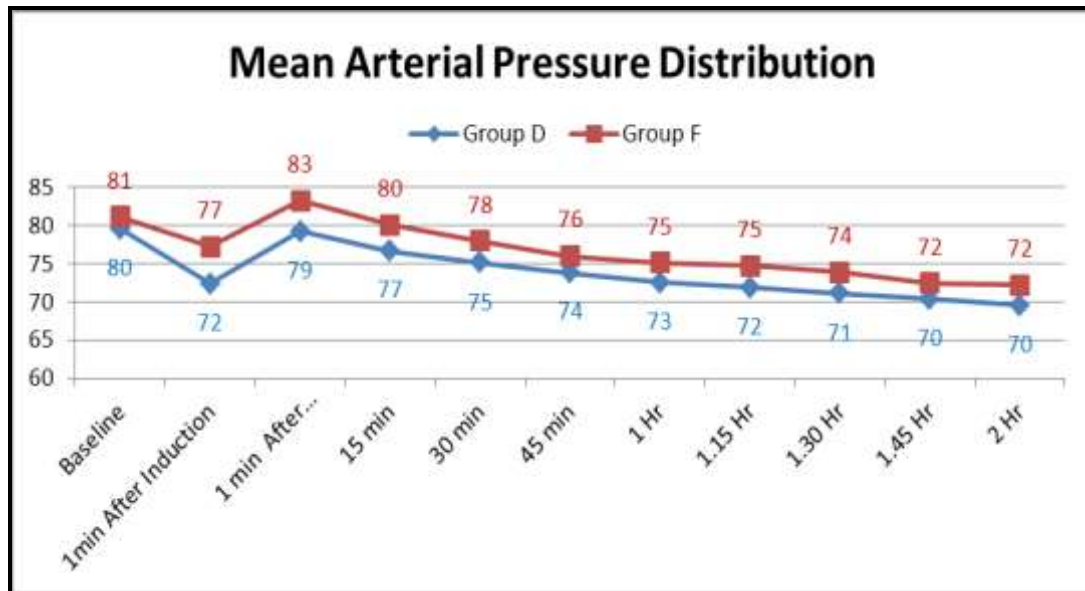
DBP



Diastolic Blood Pressure Distribution	Group D		Group F		P value Unpaired t Test
	Mean	SD	Mean	SD	
Baseline	66.00	3.47	66.20	3.47	0.8788
1min After Induction	59.40	4.21	62.76	4.21	0.7471
1 min After Intubation	66.00	3.97	68.16	3.97	0.2276
15 min	62.90	5.50	65.01	5.50	0.2286
30 min	61.45	6.02	63.16	6.02	0.2138
45 min	60.00	5.72	61.31	5.72	0.0505
1 Hr	58.40	6.50	60.61	6.50	0.0901
1.15 Hr	58.35	7.19	60.11	7.19	0.3321
1.30 Hr	57.90	6.61	59.41	6.61	0.3654
1.45 Hr	56.50	6.38	58.11	6.38	0.0744
2 Hr	55.90	7.02	57.96	7.02	0.679
2.15 Hr	56.00	5.87	57.41	5.87	0.3063
2.5 Hr	56.40	4.31	56.71	4.31	0.1511
2.45 Hr	56.00	4.09	56.81	4.09	0.0766
3 Hr	56.80	4.62	58.21	4.62	0.0439
3.15 Hr	55.20	4.13	58.88	4.13	0.1038
3.5 Hr	54.59	4.37	59.25	4.37	0.2023
3.45 Hr	55.43	5.13	62.76	5.13	0.1236
4 Hr	58.67	0.00	70.16	0.00	>0.9999
4.15 Hr	70.00	0.00	73.16	0.00	>0.9999
Post Operative	55.10	5.02	59.91	5.02	0.2822

It is evident from the diastolic blood pressure distribution table that most of the group dexmedetomidine subjects had a mean overall DBP of 58.55 mm Hg. Similarly in group fentanyl majority had a mean overall DBP of 60.49 mm Hg. ($p= 0.0853$). The data subjected to unpaired t test reveals the existence of statistically insignificant association between DBP distribution and intervention groups ($p > 0.05$).

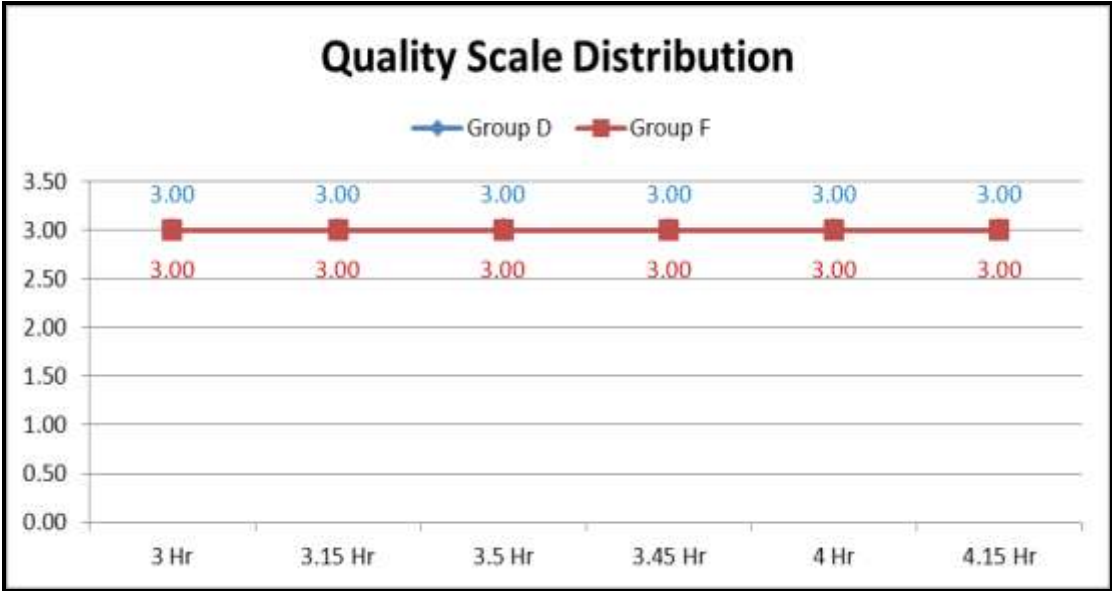
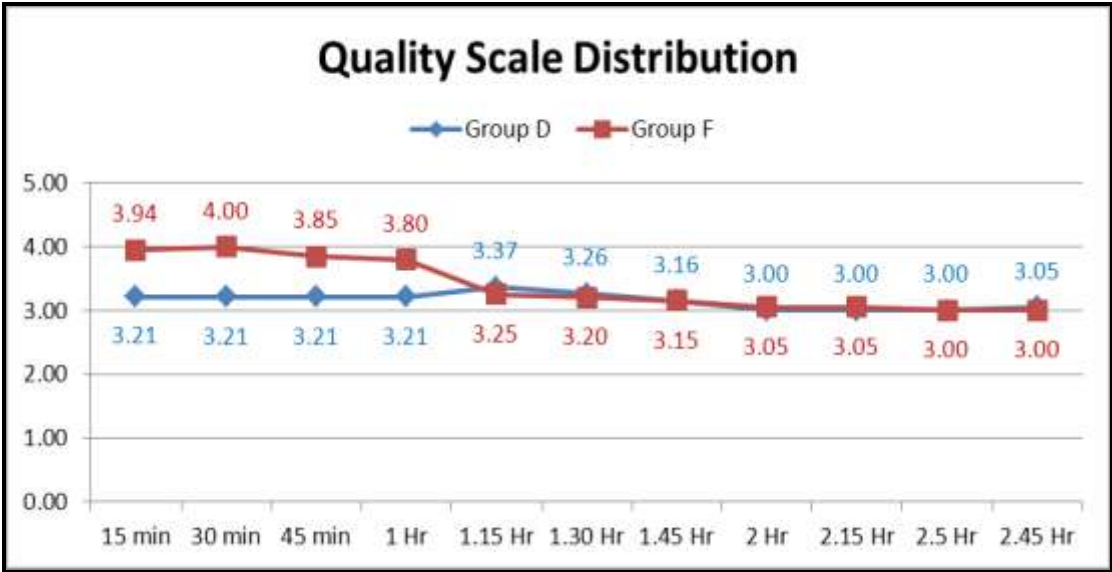
MAP



Mean Arterial Pressure Distribution	Group D		Group F		P value Unpaired t Test
	Mean	SD	Mean	SD	
Baseline	79.55	3.72	81.16	3.72	0.2849
1min After Induction	72.40	4.33	77.21	4.33	0.08
1 min After Intubation	79.20	3.56	83.27	3.56	0.7917
15 min	76.65	5.17	80.05	5.17	0.9328
30 min	75.10	5.83	78.00	5.83	0.8389
45 min	73.80	5.36	76.00	5.36	0.5012
1 Hr	72.55	5.84	75.11	5.84	0.771
1.15 Hr	71.85	7.24	74.69	7.24	0.8249
1.30 Hr	71.10	6.53	73.84	6.53	0.8496
1.45 Hr	70.35	5.96	72.48	5.96	0.7245
2 Hr	69.55	6.26	72.21	6.26	0.3226
2.15 Hr	69.65	5.55	71.69	5.55	0.1958
2.5 Hr	69.80	4.18	70.69	4.18	0.6827
2.45 Hr	69.45	4.71	71.11	4.71	0.5428
3 Hr	70.40	4.43	72.42	4.43	0.8866
3.15 Hr	69.00	4.26	73.10	4.26	0.8017
3.5 Hr	68.53	4.65	73.80	4.65	0.7812
3.45 Hr	69.29	6.23	76.56	6.23	0.7661
4 Hr	72.00	0.00	84.16	0.00	>0.9999
4.15 Hr	80.00	0.00	88.16	0.00	0.9999
Post Operative	68.95	5.38	74.69	5.38	0.6199

It is evident from the mean arterial pressure distribution table that most of the group dexmedetomidine subjects had a mean overall MAP of 72.98 mm Hg. Similarly in group fentanyl majority had a mean overall MAP of 75.96 mm Hg. ($p = 0.6734$). The data subjected to unpaired t test reveals the existence of statistically insignificant association between MAP distribution and intervention groups ($p > 0.05$).

QUALITY SCALE

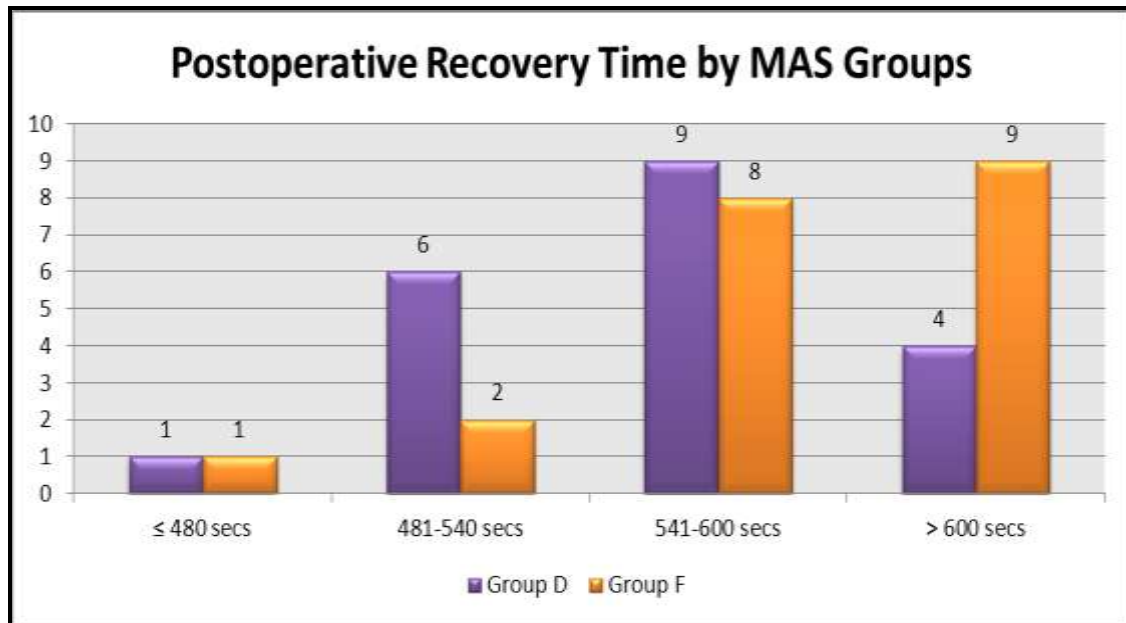


Quality Scale Distribution	Group D		Group F		P value Unpaired t Test
	Mean	SD	Mean	SD	
15 min	3.21	0.43	3.94	0.43	<0.0001
30 min	3.21	0.42	4.00	0.42	<0.0001
45 min	3.21	0.42	3.85	0.42	<0.0001
1 Hr	3.21	0.42	3.80	0.42	0.0001
1.15 Hr	3.37	0.50	3.25	0.50	0.4365
1.30 Hr	3.26	0.45	3.20	0.45	0.6503
1.45 Hr	3.16	0.37	3.15	0.37	0.9473
2 Hr	3.00	0.00	3.05	0.00	0.3364
2.15 Hr	3.00	0.00	3.05	0.00	0.3364
2.5 Hr	3.00	0.00	3.00	0.00	>0.9999
2.45 Hr	3.05	0.23	3.00	0.23	0.3112
3 Hr	3.00	0.00	3.00	0.00	>0.9999
3.15 Hr	3.00	0.00	3.00	0.00	>0.9999
3.5 Hr	3.00	0.00	3.00	0.00	>0.9999
3.45 Hr	3.00	0.00	3.00	0.00	>0.9999
4 Hr	3.00	0.00	3.00	0.00	>0.9999
4.15 Hr	3.00	0.00	3.00	0.00	>0.9999

It is evident from the quality of surgical field distribution table that most of the group dexmedetomidine subjects had a mean overall quality scale score of 2.63. Similarly in group fentanyl majority had a mean overall quality scale score of 2.76. ($p < 0.0001$).

The decreased the mean quality scale score measurement in group dexmedetomidine compared to group fentanyl is statistically significant between the period of 15 minutes to 1 hour intraoperatively. The meaningful decrease is by 18% with a mean difference of 0.69. The data subjected to unpaired t test reveals the existence of statistically significant association between quality scale score distribution and intervention groups ($p < 0.05$). This difference is true and significant and has not occurred

POSTOPERATIVE RECOVERY TIME BY MAS



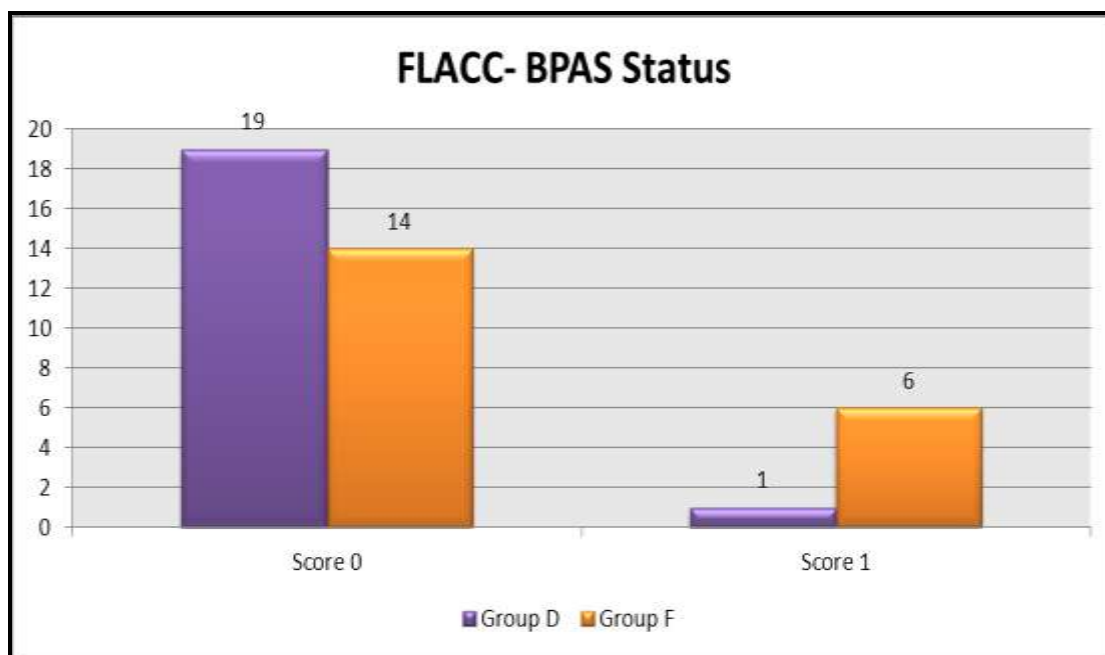
Postoperative Recovery Time by MAS Groups	Group D	%	Group F	%
≤ 480 secs	1	5.00	1	5.00
481-540 secs	6	30.00	2	10.00
541-600 secs	9	45.00	8	40.00
> 600 secs	4	20.00	9	45.00
Total	20	100.00	20	100.00

Postoperative Recovery Time by MAS Distribution	Group D	Group F
Mean	564.25	593.00
SD	50.27	51.33
P value Unpaired t Test	0.0441	

It is evident from the postoperative recovery time by MAS distribution table that most of the group dexmedetomidine subjects had a mean postoperative recovery time of 564.25 seconds. Similarly in group fentanyl majority had a mean postoperative recovery time of 593 seconds. ($p= 0.0441$).

The decreased the mean postoperative recovery time measurement in group dexmedetomidine compared to group fentanyl is statistically with a meaningful decrease is of 5% and with a mean difference of 28.75 seconds. The data subjected to unpaired t test reveals the existence of statistically significant association between postoperative recovery time distribution and intervention groups ($p < 0.05$). This difference is true and significant and has not occurred

FLACC- BPAS

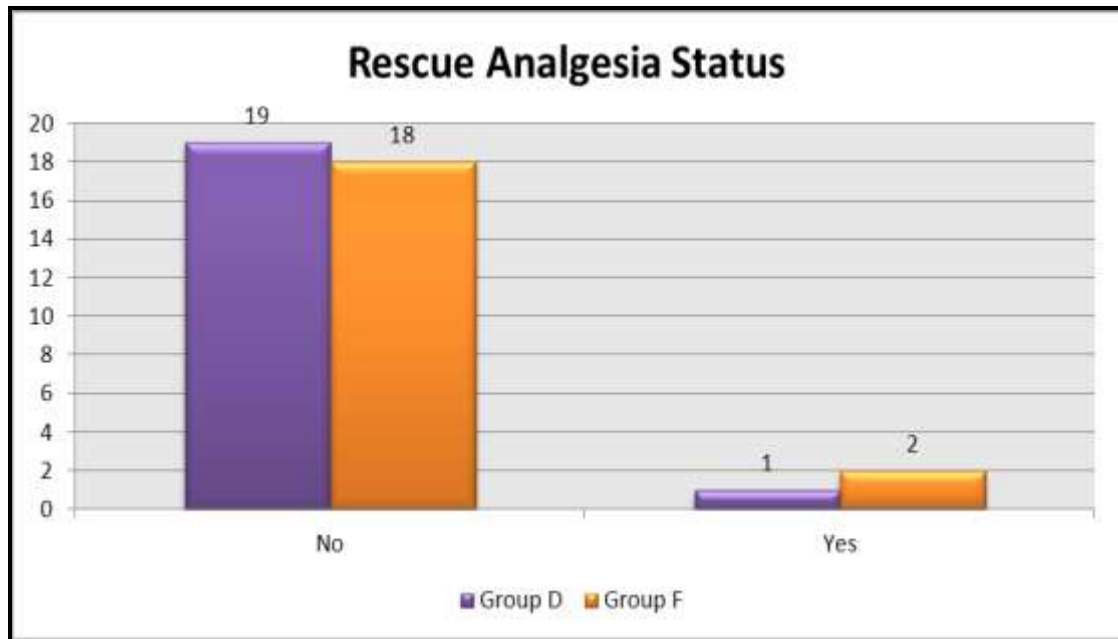


FLACC- BPAS Status	Group D	%	Group F	%
Score 0	19	95.00	14	70.00
Score 1	1	5.00	6	30.00
Total	20	100.00	20	100.00
P value Fishers Exact Test			0.0449	

It is evident from the FLACC - BPS status table that 95% of the group dexmedetomidine subjects had FLACC – BPS score 0. Similarly 70% of group fentanyl majority had FLACC – BPS score 0. (p= 0.0449).

The increased incidence of FLACC – BPS score 0 in group dexmedetomidine compared to group fentanyl is statistically with a meaningful increase of 26% and with a percentage difference of 25.00 points. The data subjected to fishers exact test reveals the existence of statistically significant association between postoperative recovery time distribution and intervention groups ($p < 0.05$). This difference is true and significant and has not occurred

RESCUE ANALGESIA



Rescue Analgesia Status	Group D	%	Group F	%
No	19	95.00	18	90.00
Yes	1	5.00	2	10.00
Total	20	100.00	20	100.00
P value Fishers Exact Test			0.6186	

It is evident from the rescue analgesia status table that most of the group dexmedetomidine subjects did not need rescue analgesia (95%) and in group fentanyl majority too did not need rescue analgesia (90%) ($p=0.6186$). The data subjected to fishers exact test reveals the existence of statistically insignificant association between did not need rescue analgesia status and intervention groups ($p > 0.05$)

DISCUSSION

General Anaesthesia is a commonly used anaesthetic technique for cochlear Implantation surgeries in paediatric patients. In this study, intravenous infusion dose of Dexmedetomidine 0.4mcg/kg/hr versus FENTANYL 1mcg/kg/hr and their post operative recovery time was studied in 40 patients undergoing elective cochlear Implantation surgery.

POST OPERATIVE RECOVERY TIME

The mean post operative recovery time for Dexmedetomidine group was 564.25 seconds and for Fentanyl group was 593 seconds. Patients in the dexmedetomidine group have significantly and consistently quicker post operative recovery time.

Mohammed Hafez El Saied et al who compared the intravenous infusion dose of Dexmedetomidine 0.4mcg/kg/hr versus Fentanyl 1mcg/kg/hr in post operative recovery time and observed that recovery time was significantly shorter for the patients in D group than in F group.

Gupta N et al did a comparative study between dexmedetomidine and volume matched saline (placebo) and found

that intraoperative use of Dexmedetomidine has a shorter recovery time.

Goyal S et al who compared the effect of 0.25mcg/kg/hr maintenance dose of dexmedetomidine vs fentanyl 0.5mcg/kg/hr and observed that dexmedetomidine has better recovery profile than fentanyl.

POST OPERATIVE PAIN

In our study, the increased incidence of FLACC- BPS Score 0 in group D compared to group F is statistically with a meaningful increase of 26% and we conclude that post operative pain was significantly and consistently lower with dexmedetomidine compared to fentanyl.

Mohamed Hafez El Saied et al who compared the IV infusion dose of Dexmedetomidine 0.4mcg/kg/hr versus Fentanyl 1mcg/kg/hr in post operative pain and observed that post operative pain were not different between the two groups.

Gupta N et al did a comparative study between dexmedetomidine and volume matched saline (placebo) and found that group D patients has reduced post operative pain.

Hwang W, Lee J, Park J, Joo J et al who compared the effect of

0.01-0.02 mcg/kg/min dexmedetomidine vs remifentanyl 0.01-0.02 mcg/kg/min in post operative pain control and found that Dexmedetomidine displayed superior efficacy in alleviating pain and in post operative pain management.

INTRA OPERATIVE HEMODYNAMICS

In our study, dexmedetomidine subjects had a mean overall heart rate of 114.87 beats per minute and fentanyl subjects had a mean overall heart rate of 117.65 beats per min.

Dexmedetomidine group had a mean overall Systolic Blood Pressure of 98.76 mmHg and Fentanyl group had a mean overall Systolic Blood Pressure of 101.66 mmHg.

Dexmedetomidine group had a mean overall Diastolic Blood Pressure of 58.55 mmHg and Fentanyl group had a mean overall Diastolic Blood Pressure of 60.49 mmHg.

Dexmedetomidine group had a mean overall Mean Arterial Pressure of 72.98 mmHg and fentanyl group had a mean overall Mean Arterial Pressure of 75.96 mmHg.

We conclude that there is a existence of statistically insignificant association between Heart Rate, Systolic Blood

Pressure, Diastolic Blood Pressure, Mean Arterial Pressure distribution between dexmedetomidine and fentanyl group.

Mohamed Hafez El Saied et al who compared the IV infusion dose of dexmedetomidine 0.4 mcg/kg/hr versus Fentanyl 1 mcg/kg/hr in intra operative hemodynamics and observed that group D showed a decreased heart rate and mean arterial pressure than fentanyl group and was better in inducing deliberate hypotension and statistically significant.

Gupta N et al did a comparative study between dexmedetomidine and volume matched saline (placebo) and found that dexmedetomidine group had bradycardia and hypotension and statistically significant.

Goyal S et al who compared the effect of 0.25 mcg/kg/hr maintenance dose of Dexmedetomidine vs fentanyl 0.5 mcg/kg/hr and observed that mean intraoperative hemodynamics was less in group D compared to group F with significant p value.

QUALITY OF THE SURGICAL FIELD

In our study, mean overall quality scale for Dexmedetomidine was 2.63 and for Fentanyl was 2.76 and found that

dexmedetomidine has better quality of the surgical field compared to Fentanyl.

Mohamed Hafez El Sailed et al who compared the IV infusion dose of Dexmedetomidine 0.4 mcg/kg/hr versus Fentanyl 1 mcg/kg/hr in quality of the surgical field and observed that group D has better quality of the surgical field compared to Fentanyl infusion.

Passaint Fahim Hassan, Amany Hassan Saleh et al who compared the effect of 0.4 mcg/kg/hr dexmedetomidine continuous infusion versus 10mg/kg/hr Magnesium sulfate continuous infusion in providing better quality of the surgical field and observed that dexmedetomidine have superior effect on the surgical field.

Sabry Mohamed Amin et al who conducted the study to determine the efficacy of 0.2-0.5mcg/kg/hr continuous infusion of Dexmedetomidine versus 100- 300 mcg/kg/min continuous infusion of Esmolol and observed that Dexmedetomidine ensured good surgical field during surgery.

NEED FOR RESCUE ANALGESIA

In our study, there is no need for post operative analgesia in both groups.

Mohamed Hafez El Saied et al who compared the IV infusion dose of Dexmedetomidine 0.4mcg/kg/hr versus Fentanyl 1 mcg/kg/hr and observed that group D has reduced need for pain medication in the PACU.

Goyal S et al who compared the effect of 0.25 mcg/kg/hr maintenance dose of Dexmedetomidine vs Fentanyl 0.5 mcg/kg/hr and observed that group D has reduced need for post operative pain management.

SUMMARY

This double blinded prospective randomized controlled trial was designed to compare the post operative recovery time by MAS, as well as to assess the post operative pain by FLACC, intra operative hemodynamics, quality of the surgical field, need for rescue analgesia of Dexmedetomidine versus Fentanyl given intravenous infusion for paediatric patients scheduled for cochlear Implantation surgery, patients receiving IV fentanyl Infusion served as the control.

The following observations were made : Dexmedetomidine have significantly and consistently quicker post operative recovery time.

Dexmedetomidine have lower post operative pain when compared to Fentanyl. Dexmedetomidine have lower intra operative hemodynamics when compared to Fentanyl though statistically insignificant. Dexmedetomidine have better quality of the surgical field when compared with Fentanyl. Dexmedetomidine group has reduced need for post operative pain management.

CONCLUSION

Dexmedetomidine infusion in Cochlear Implantation in paediatric patients seems to be a good alternative to Fentanyl infusion since it produces quicker post operative recovery time and reducing post operative pain with better quality of the surgical field and reduced need for rescue analgesia. Dexmedetomidine was well tolerated with no clinically significant effects on blood pressure or heart rate.

BIBLIOGRAPHY

- 1) Hwang W, Lee J, Park J, Joo J, Dexmedetomidine versus remifentanyl in post operative pain control after spinal surgery BMC Anesthesiol 2015; 15:21
- 2) Dr. Marcia L. Buck, Douglas F. Willson, use of Dexmedetomidine in the paediatric Intensive care unit vol.28, issue 1, p 51-57.
- 3) Berrin Isik, Mustafa Arslan, Alper Dogan Tunga, Omer Kurtipek Dexmedetomidine decreases emergence agitation in paediatric patients after sevoflurane anesthesia without surgery vol 16, issue 7, p.748-753.
- 4) Aynur Akin, Adnan Bayram, Aliye Esmaoglu Dexmedetomidine vs midazolam for premedication of pediatric patients undergoing anesthesia, pediatric anesthesia vol 22, p 871-876.
- 5) Sabry Mohamed Amin , Mohamed Gamal Eldin Elmawy, optimizing surgical field during Cochlear Implant surgery in children: Dexmedetomidine versus Esmolol; Egyptian Journal of Anaesthesia vol 32 p 255-261.

- 6) Mohamed Hafez Saied et al, Dexmedetomidine versus Fentanyl in anesthesia of cochlear Implantation in pediatric patients; Egyptian Journal of Anaesthesia Jan 2016, vol 32 p 55-59.
- 7) Passaint Fahim Hassan et al, Amany Hassan Saleh et al, Dexmedetomidine versus magnesium sulfate in anesthesia for cochlear Implantation surgery in pediatric patients, Anesthesia Essays and Researches.
- 8) Goksu S, Arik H, Demiryurek S, Effects of dexmedetomidine infusion in patients undergoing functional endoscopic sinus surgery under local anaesthesia; Eur J Anaesthesiol 2008; 25(1): 22-8.
- 9) Goyal S, Gupta KK, Mahajan V, A comparative Evaluation of Intravenous Dexmedetomidine and Fentanyl in Breast cancer surgery; Anesth Essays Res. 2017, 11(3).
- 10) Gupta N et al, Effect of Intraoperative dexmedetomidine on post operative recovery profile of children undergoing surgery for spinal dysraphism, J Neurosurg Anesthesiol 2013.

- 11) Joseph D.Tobias, John W.Berkenbosch, Initial experience with dexmedetomidine in paediatric aged patients; pediatric anesthesia vol 12; p 171-175.
- 12) Joyshankar J Jana, Neelam Vaid, Jyoti Shanbhag Effect of total intravenous anaesthesia on intraoperative monitoring of Cochlear implant function in paediatric patients, Cochlear Implants International vol 14, 2013.
- 13) Jana JJ, Vaid N, Shanbhag J Effect of total intravenous anaesthesia on intraoperative monitoring of cochlear implant function in paediatric patients. C ochlear Implants Int. 2013 Jun;14(3):169-73
- 14) Joseph S.Yeh ,Kimberly L. Mooney Anesthetic complications in pediatric patients undergoing cochlear implantation pediatric Ears,Vol 121, October 2011 P 2240–2244

**INSTITUTIONAL ETHICS COMMITTEE
MADRAS MEDICAL COLLEGE, CHENNAI 600 003**

EC Reg.No.ECR/270/Inst./TN/2013
Telephone No.044 25305301
Fax: 011 25363970

CERTIFICATE OF APPROVAL

To
Dr.A.Azmal Khan
II Year Post Graduate in MD Anaesthesiology
Institute of Anaesthesiology & Critical Care
Madras Medical College
Chennai 600 003



Dear Dr.A.Azmal Khan,

The Institutional Ethics Committee has considered your request and approved your study titled **"A COMPARATIVE STUDY OF DEXMEDETOMIDINE VERSUS FENTANYL AS AN ANAESTHETIC ADJUVANT IN ANAESTHESIA FOR COCHLEAR IMPLANTATION IN PAEDIATRIC PATIENTS "** - NO.17022017 (II)

The following members of Ethics Committee were present in the meeting hold on **21.02.2017** conducted at Madras Medical College, Chennai 3

- | | |
|---|---------------------|
| 1.Dr.C.Rajendran, MD., | :Chairperson |
| 2.Dr.M.K.Muralidharan,MS.,M.Ch.,Dean, MMC,Ch-3 | :Deputy Chairperson |
| 3.Prof.Sudha Seshayyan,MD., Vice Principal,MMC,Ch-3 | : Member Secretary |
| 4.Prof.B.Vasanthi,MD., Prof.of Pharmacology.,MMC,Ch-3 | : Member |
| 5.Prof.K.Ramadevi,MD.,Director,Inst.of Bio-Che,MMC,Ch-3 | : Member |
| 6.Tmt.J.Rajalakshmi, JAO,MMC, Ch-3 | : Lay Person |
| 7.Thiru S.Govindasamy, BA.,BL,High Court,Chennai | : Lawyer |
| 8.Tmt.Arnold Saulina, MA.,MSW., | :Social Scientist |

We approve the proposal to be conducted in its presented form.

The Institutional Ethics Committee expects to be informed about the progress of the study and SAE occurring in the course of the study, any changes in the protocol and patients information/informed consent and asks to be provided a copy of the final report.

Member Secretary – Ethics Committee

MEMBER SECRETARY
INSTITUTIONAL ETHICS COMMITTEE
MADRAS MEDICAL COLLEGE
CHENNAI-600 003

Urkund Analysis Result

Analysed Document: Plagiarism_Dr.Azmal.doc (D31520890)
Submitted: 10/21/2017 10:13:00 AM
Submitted By: azmalkhan.a@gmail.com
Significance: 17 %

Sources included in the report:

FINAL DOLKAR THESIS 2016.docx (D22862333)
COMPARSION EFFECT OF PLAIN BUPIVACAINE VS BUPIVACAINE WITH FENTANYL VS
BUPIVACAINE WITH DEXMEDITOMIDINE INTRATHECALLY ON SPINAL BLOCK
CHARACTERISTICS IN LOWER ABDOMINAL SURGICAL PROCEDURES DOUBLE BLINDED
CONTROL STU.pdf (D31258525)
puni1 dissertation-2 (1).pdf (D31391447)
<http://wps.prenhall.com/wps/media/objects/3103/3178396/tools/flacc.pdf>

Instances where selected sources appear:

40

PLAGIARISM CERTIFICATE

This is to certify that this dissertation work titled “A COMPARATIVE STUDY OF DEXMEDETOMIDINE VS FENTANYL AS AN ANAESTHETIC ADJUVANT IN ANAESTHESIA FOR COCHLEAR IMPLANTATION IN PAEDIATRIC PATIENTS DOUBLE BLINDED CONTROL STUDY” of the candidate Dr.AZMAL KHAN.A with Registration Number 201520013 for the award of M.D ANAESTHESIOLOGY. I personally verified the urkund.com website for plagiarism check. I found that the uploaded file containing introduction to conclusion pages shows a result of 17% plagiarism in this dissertation.

Guide and supervisor sign with seal

PATIENT CONSENT FORM

Study title "A COMPARATIVE STUDY OF DEXMEDETOMIDINE VERSUS FENTANYL AS AN ANAESTHETIC ADJUVANT IN ANAESTHESIA FOR COCHLEAR IMPLANTATION IN PAEDIATRIC PATIENTS".

(A prospective randomized, double blinded controlled study for assessing the post operative recovery time using dexmedetomidine (0.4 mcg/kg) and fentanyl (1mcg/kg))

Study center: INSTITUTE OF ANAESTHESIOLOGY AND CRITICAL CARE,
RAJIV GANDHI GOVT. GENERAL HOSPITAL,
MADRAS MEDICAL COLLEGE,
CHENNAI-0 3.

Participant name: _____ Age: _____ Sex: _____ I.P.No: _____

I confirm that I have understood the purpose of procedure for the above study. I have the opportunity to ask the question and all my questions and doubts have been answered to my satisfaction.

I have been explained about the pitfall in the procedure. I have been explained about the safety, advantage and disadvantage of the technique.

I understand that my participation in the study is voluntary and that I am free to withdraw at anytime without giving any reason.

I understand that investigator, regulatory authorities and the ethics committee will not need my permission to look at my health records both in respect to current study and any further research that may be conducted in relation to it, even if I withdraw from the study. I understand that my identity will not be revealed in any information released to third parties or published, unless as required under the law. I agree not to restrict the use of any data or results that arise from the study.

Time:

Date: _____ Signature / thumb impression of patient _____

Place: _____ Patient name: _____

Signature of the investigator:

Name of the investigator:

INFORMATION TO PARTICIPENTS

Investigator : Dr.A.AZMAL KHAN

Name of the Participant:

Title: "A COMPARATIVE STUDY OF DEXMEDETOMIDINE VERSUS FENTANYL AS AN ANAESTHETIC ADJUVANT IN ANAESTHESIA FOR COCHLEAR IMPLANTATION IN PAEDIATRIC PATIENTS".

(A prospective randomized, double blinded controlled study for assessing the post operative recovery time using dexmedetomidine (0.4 mcg/kg) and fentanyl (1mcg/kg))

You are invited to take part in this research study. We have got approval from the IEC. You are asked to participate because you satisfy the eligibility criteria. We want to compare the post operative recovery time by modified aldrete recovery score using dexmedetomidine and Fentanyl in cochlear implantation surgery for paediatric patients.

What is the Purpose of the Research

To assess post operative recovery time by modified aldrete recovery score

To assess post operative pain by FLAC behavioral pain assessment scale

To assess intraoperative hemodynamics

To assess the quality of the surgical field

To assess need for rescue analgesia and antiemetic in PACU

The Study Design:

All the patients in the study will be divided into two groups.

GroupD-DEXMEDETOMIDINE GROUP

GroupF-Fentanyl group

Benefits

By using these two drugs post operative recovery time can be decreased, provides better post operative pain relieve, optimise the intraoperative hemodynamics, provides better quality of the surgical field. This intervention has been shown to be well tolerated as shown by previous studies. And if you do not want to participate you will have alternative of setting the standard treatment and your safety is our prime concern.

Time :

Date :

Place :

Signature / Thumb Impression of Patient

Patient Name:

Signature of the Investigator : _____

Name of the Investigator : _____

ஆராய்ச்சி ஒப்புதல் படிவம்

ஆராய்ச்சி தலைப்பு :

காக்கியார் இம்பளண்டேஷன் அறுவை சிகிச்சைக்கு மயக்கத் துணை மருந்துகளாக டெக்ஸ்மெடிடோமிடின் மற்றும் பென்டானில் மருந்தினை செலுத்தி, அறுவை சிகிச்சைக்குப் பிறகு மயக்கத்திலிருந்து மீண்டு வரும் நேரத்தின் தன்மை அடிப்படையில் ஒப்பிடுதல்.

ஆராய்ச்சி நிலையம் : மயக்கவியல் துறை,
இராஜீவ் காந்தி அரசு பொது மருத்துவமனை மற்றும்
சென்னை மருத்துவக் கல்லூரி,
சென்னை - 600 003.

பங்கு பெறுபவரின் பெயர் :

உறவுமுறை :

பங்கு பெறுபவரின் எண். :

பங்கு பெறுபவர் இதனை (✓) குறிக்கவும்

மேலே குறிப்பிட்டுள்ள மருத்துவ ஆய்வின் விவரங்கள் எனக்கு விளக்கப்பட்டது. என்னுடைய சந்தேகங்களை கேட்கவும், அதற்கான தகுந்த விளக்கங்களைப் பெறவும் வாய்ப்பளிக்கப்பட்டது.

☐

நான் இவ்ஆய்வில் தன்னிச்சையாகத்தான் பங்கேற்கிறேன். எந்தக் காரணத்தினாலோ எந்தக் கட்டத்திலும் எந்த சட்ட சிக்கலுக்கும் உட்படாமல் நான் இவ்ஆய்வில் இருந்து விலகிக் கொள்ளலாம் என்றும் அறிந்து கொண்டேன்.

☐

இந்த ஆய்வு சம்மந்தமாகவோ, இதை சார்ந்த மேலும் ஆய்வு மேற்கொள்ளும்போதும் இந்த ஆய்வில் பங்குபெறும் மருத்துவர் என்னுடைய மருத்துவ அறிக்கைகளைப் பார்ப்பதற்கு என் அனுமதி தேவையில்லை என அறிந்து கொள்கிறேன். நான் ஆய்வில் இருந்து விலகிக் கொண்டாலும் இது பொருந்தும் என அறிகிறேன்.

☐

இந்த ஆய்வின் மூலம் கிடைக்கும் தகவல்களையும், பரிசோதனை முடிவுகளையும் மற்றும் சிகிச்சை தொடர்பான தகவல்களையும் மருத்துவர் மேற்கொள்ளும் ஆய்வில் பயன்படுத்திக் கொள்ளவும் அதைப் பிரசுரிக்கவும் என் முழு மனதுடன் சம்மதிக்கிறேன்.

☐

இந்த ஆய்வில் பங்கு கொள்ள ஒப்புக்கொள்கிறேன். எனக்குக் கொடுக்கப்பட்ட அறிவுரைகளின்படி நடந்து கொள்வதுடன், இந்த ஆய்வை மேற்கொள்ளும் மருத்துவ அணிக்கு உண்மையுடன் இருப்பேன் என்றும் உறுதியளிக்கிறேன்.

☐

பங்கேற்பவரின் கையொப்பம்..... இடம்..... தேதி
கட்டைவிரல் ரேகை

பங்கேற்பவரின் பெயர் மற்றும் விலாசம்.....

ஆய்வாளரின் கையொப்பம்..... இடம்..... தேதி

ஆய்வாளரின் பெயர்.....

ஆராய்ச்சி தகவல் தாள்

ஆராய்ச்சியாளர் பெயர் : மருத்துவர். அ. அஜ்மல் கான்

பங்கேற்பாளர் பெயர் :

ஆராய்ச்சி தலைப்பு :

காக்ளியர் இம்பளண்டேஷன் அறுவை சிகிச்சைக்கு மயக்கத் துணை மருந்துகளாக டெக்ஸ்மெதிடோமிடின் மற்றும் பென்டனில் மருந்தினை செலுத்தி, அறுவை சிகிச்சைக்குப் பிறகு மயக்கத்திலிருந்து மீண்டு வரும் நேரத்தின் தன்மை அடிப்படையில் ஒப்பிடுதல்.

ஆராய்ச்சியின் நோக்கம்:

காக்ளியர் இம்பளண்டேஷன் அறுவை சிகிச்சைக்கு மயக்கத்திற்கு துணை மருந்துகளாக டெக்ஸ்மெதிடோமிடின் மற்றும் பென்டனில் மருந்தினை செலுத்தி, அறுவை சிகிச்சைக்குப் பிறகு மயக்கத்திலிருந்து மீண்டு வரும் தன்மையை மாடிபைடு அல்ரீடு ரெக்கவரி ஸ்கோர் மூலம் ஒப்பீடு செய்தல்.

1. அறுவை சிகிச்சைக்கு பின்பு, FLACC பிகேவியர் அளவுகோலின் படி வலியின் அளவு.
2. அறுவை சிகிச்சையின் போது நாடித்துடிப்பு, இரத்த அழுத்தம்
3. அறுவை சிகிச்சை களத்தின் தரத்தை அறிதல்
4. அறுவை சிகிச்சைக்குப் பிறகு, இதர வலி நிவாரணிகள் மற்றும் வாந்தி வராமல் இருக்க மருந்தின் தேவையை அறிதல்.

ஆய்வின் தன்மை:

ஆய்வின் தன்மை:

ஆய்வில் பங்கு பெறும் நோயாளிகள் இரண்டு குழுக்களாகப் பிரிக்கப்படுவர்.

குழு 1 : துணை மருந்தாக டெக்ஸ்மெதிடோமிடின் செலுத்தப்பட்டவர்கள்.

குழு 2 : துணை மருந்தாக பென்டனைல் செலுத்தப்பட்டவர்கள்.

நன்மைகள்:

1. மயக்கத்திலிருந்து மீண்டு வரும் நேரம் குறைக்கப்படுகின்றன.
2. அறுவை சிகிச்சையின் போது நாடித் துடிப்பு மற்றும் இரத்த அழுத்தம் சீராக செயல்பட உதவுகின்றன.
3. இதர வலி நிவாரணிகளின் தேவை வெகுவாக குறைக்கப்படுகின்றன.

பக்க விளைவுகள்:

குறைந்த இரத்த அழுத்தம், குறைந்த நாடித்துடிப்பு ஏற்படலாம். அதற்கு மாற்று மருந்துகள் உடனடியாகக் கொடுக்கப்படும்.

இந்த முறையான ஆய்வு ஏற்கனவே பல இடங்களில் நடத்தப்பட்டுள்ளது. மேலும் இதன் பாதுகாப்பு உறுதிசெய்யப்பட்டுள்ளது. நீங்கள் இந்த ஆய்வில் பங்குகொள்ள விரும்பவில்லை என்றால் எப்போதும் உபயோகிக்கப்படும் மருந்தே கொடுக்கப்படும். உங்கள் பாதுகாப்பே எங்களின் முக்கிய நோக்கம்.

இந்த ஆய்வு சம்பந்தமாக எல்லா புள்ளி விவரங்கள் மற்றும் நோயாளிகளின் விவரங்கள் ரகசியமாக வைக்கப்படும். இந்த ஆய்வு சம்பந்தப்பட்ட எல்லா பரிசோதனைகள், மருந்துகள் மற்றும் மருத்துவ சேவைகள் அனைத்தும் நோயாளிகளுக்கு இலவசமாக வழங்கப்படும்.

ஆய்வாளரின் பெயர்

பங்குகொள்பவரின் /
பாதுகாவலரின் பெயர்

ஆய்வாளரின் கையொப்பம்

பங்குபெறுபவரின் கையொப்பம் /
கட்டை விரல் ரேகை

PROFORMA

DATE:

ROLL NO:

AIRWAY DEVICE:

NAME:

AGE:

SEX:

IP NO:

DIAGNOSIS:

SURGICAL PROCEDURE DONE:

Ht:

CVS:

HB:

Wt:

RS:

AIRWAY:MMC -

IID -

DENTITION -

PRE OP ASSESSMENT:

HISTORY: Any Co-morbid illness

H/O Documented Difficult Airway

H/O previous surgeries

MEASURES OF STUDY OUTCOME:

INTUBATION RESPONSE:

Premedication:

induction:

Intubation:

Maintenance:

Positioning;

Drugs

COMPLICATIONS IN INTRA OPERATIVE PERIOD:

COMPLICATIONS POST EXTUBATION:

HEMODYNAMICS:INTRA OPERATIVE

[illegible]

POST OPERATIVE

[illegible]

GROUP-D

S. No	Name	Age	Age/																				
		Sex	Sex	Baseline						1min after induction					1 min after intubation					15 min			
				IP NO	HR	SBP	DBP	MAP	Qua.Sc ale	HR	SBP	DBP	MAP	Qua.S cale	HR	SBP	DBP	MAP	Qua.S cale	HR	SBP	DBP	MAP
1	pradeep	3	1	53654	126	100	60	73		116	90	54	66		122	111	62	78		101	98	58	71
2	muthulakshmi	3	2	52265	116	100	60	73		111	90	54	66		126	110	72	85		120	111	76	88
3	yuvasree	3	2	49326	128	100	60	73		126	88	52	64		138	126	88	100		134	121	82	95
4	rashika	4	2	46071	152	118	70	86		146	111	68	82		148	118	76	90		141	112	72	85
5	astika	2	2	61367	156	100	60	73		145	88	54	65		150	100	62	75		141	98	60	73
6	yogesh	4	1	53912	144	118	76	90		138	102	64	77		140	108	72	84		136	110	72	85
7	vishnu	2	1	50516	136	111	68	82		130	101	58	72		134	109	66	80		126	111	64	80
8	movendran	3	1	53654	126	98	64	75		119	90	54	66		121	94	66	75		118	92	60	71
9	yashini	2	2	54675	121	102	62	75		116	98	56	70		120	102	62	75		114	101	58	72
10	ramesh	3	1	60746	132	118	74	89		128	104	64	77		133	110	68	82		126	109	58	75
11	babu	2	1	62734	136	106	68	81		128	99	60	73		132	102	64	77		128	102	62	75
12	priya	4	2	59432	128	106	66	79		124	99	62	74		126	102	62	75		121	100	60	73
13	darshan	2	1	54432	118	116	66	83		114	111	64	80		118	114	68	83		114	112	64	80
14	ganesh	3	1	59432	134	106	66	79		130	104	62	76		132	106	62	77		126	102	58	73
15	vijaya	2	2	60024	126	104	66	79		122	98	56	70		124	102	62	75		119	102	58	73
16	ramkumar	3	1	61240	138	118	72	87		132	108	64	79		136	106	62	77		132	112	60	77
17	indira	3	2	58432	118	104	64	77		114	99	62	74		116	102	64	77		114	102	62	75
18	rani	2	2	58439	128	111	62	78		124	99	58	72		126	99	62	74		121	98	62	74
19	kasi	3	1	58646	134	108	68	81		126	99	62	74		130	98	56	70		126	96	54	68
20	revathi	3	2	56943	121	99	68	78		116	94	60	71		118	96	64	75		114	94	58	70

S. No																										
		30 min					45 min					1 Hr					1.15 Hr					1.30 Hr				
	Qua.S cale	HR	SBP	DBP	MAP	Qua.S cale	HR	SBP	DBP	MAP	Qua.S cale	HR	SBP	DBP	MAP	Qua.S cale	HR	SBP	DBP	MAP	Qua.S cale	HR	SBP	DBP	MAP	Qua.S cale
1		110	100	60	73	3	115	100	67	78	3	114	100	60	73	3	111	97	63	74	4	111	95	62	73	4
2		118	106	71	83	3	114	104	68	80	3	111	102	64	77	3	111	101	64	76	4	106	101	66	78	4
3		130	120	82	95	3	130	118	74	89	3	124	116	74	88	3	124	110	72	85	3	121	109	68	82	3
4	3	136	108	70	83	3	132	108	71	83	3	131	106	68	81	3	126	104	64	77	3	124	102	62	75	3
5	3	140	98	60	73	3	136	96	58	71	4	136	94	56	69	4	132	92	56	68	4	130	90	54	66	4
6	3	134	108	68	81	3	132	104	64	77	3	132	104	66	79	3	128	106	62	77	4	126	102	60	74	4
7		124	108	62	77	3	124	108	60	76	3	120	106	60	75	3	114	104	58	73	3	114	102	54	70	3
8		116	92	58	69		116	94	56	69		114	94	58	70		109	94	56	69		109	92	54	67	
9	3	111	98	56	70	3	110	96	54	68	3	99	96	52	67	3	98	94	54	67	3	98	92	56	68	3
10	3	124	108	60	76	3	124	106	62	77	3	118	104	60	75	3	120	106	60	75	3	122	102	62	75	3
11	3	124	99	60	73	3	122	98	58	71	3	122	98	56	70	3	124	96	56	69	3	118	94	54	67	3
12	3	116	99	58	72	3	118	98	56	70	3	118	96	56	69	3	114	96	54	68	4	112	94	58	70	4
13	3	116	109	62	78	3	114	108	62	77	3	111	108	56	73	4	109	104	58	73	4	108	106	58	74	3
14	3	128	99	58	72	3	124	96	56	69	3	120	96	54	68	3	122	94	58	70	3	118	94	58	70	3
15	3	118	99	54	69	3	118	98	54	69	3	114	94	52	66	3	106	94	56	69	3	108	96	54	68	3
16	3	130	110	60	77	4	132	108	54	72	4	126	106	56	73	3	121	104	56	72	3	122	104	54	71	3
17		112	100	58	72	4	110	102	56	71	4	112	99	54	69	4	114	98	56	70	3	112	98	58	71	3
18	4	118	98	60	73	4	116	99	58	72	4	114	102	58	73	4	114	104	56	72	3	112	99	56	70	3
19	4	122	96	56	69	4	122	98	56	70	3	118	98	54	69	3	116	94	56	69	4	116	94	58	70	3
20	4	112	90	56	67	3	110	90	56	67	3	110	92	54	67	3	104	88	52	64	3	106	86	52	63	3

S. No	Intra Operative -																									
	1.45 Hr					2 Hr					2.15 Hr					2.5 Hr					2.45 Hr					
	HR	SBP	DBP	MAP	Qua.S cale	HR	SBP	DBP	MAP	Qua.S cale	HR	SBP	DBP	MAP	Qua.S cale	HR	SBP	DBP	MAP	Qua.S cale	HR	SBP	DBP	MAP	Qua.S cale	HR
1	114	100	56	71	4	100	100	58	72	3	96	100	60	73	3	85	95	60	72	3	102	90	54	66	3	106
2	106	101	58	72	3	101	99	54	69	3	99	99	54	69	3	94	98	56	70	3	92	101	54	70	3	92
3	120	108	66	80	3	118	108	66	80	3	118	110	64	79	3	116	110	62	78	3	116	110	62	78	3	118
4	124	102	62	75	3	116	98	60	73	3	112	96	60	72	3	111	96	58	71	3	114	94	60	71	3	112
5	128	90	54	66	3	130	94	56	69	3	130	90	58	69	3	126	92	58	69	3	124	92	58	69	3	126
6	124	98	58	71	3	122	96	56	69	3	122	96	56	69	3	124	96	54	68	3	126	94	58	70	3	122
7	112	99	56	70	3	110	98	54	69	3	110	98	54	69	3	109	99	54	69	3	111	98	52	67	3	108
8	104	96	52	67		102	96	52	67		104	94	54	67		101	94	54	67		99	92	56	68		98
9	96	96	58	71	3	96	99	58	72	3	94	102	62	75	3	94	106	62	77	3	96	102	60	74	3	102
10	118	104	62	76	3	116	98	60	73	3	112	98	56	70	3	112	96	54	68	3	110	102	52	69	3	112
11	116	98	52	67	3	116	98	52	67	3	118	96	54	68	3	112	96	58	71	3	114	94	56	69	4	109
12	106	92	56	69	3	108	92	54	67	3	106	96	52	67	3	104	98	58	71	3	104	94	58	70	3	102
13	110	104	56	72	4	104	102	54	70	3	102	99	52	68	3	102	98	54	69	3	104	102	54	70	3	99
14	114	98	56	70	4	116	92	54	67	3	110	92	52	65	3	114	94	54	67	3	116	96	56	69	3	109
15	108	96	54	68	3	106	88	52	64	3	104	96	54	68	3	102	94	54	67	3	108	94	52	66	3	110
16	118	102	52	69	3	120	96	52	67	3	114	96	54	68	3	112	98	56	70	3	110	96	58	71	3	110
17	104	96	58	71	3	106	96	56	69	3	102	94	56	69	3	99	92	54	67	3	98	96	52	67	3	98
18	110	96	54	68	3	99	94	60	71	3	98	94	58	70	3	106	92	58	69	3	108	92	60	71	3	108
19	114	96	58	71	3	114	102	56	71	3	116	104	54	71	3	112	96	52	67	3	110	94	52	66	3	114
20	106	86	52	63	3	104	88	54	65	3	102	88	56	67	3	99	90	58	69	3	98	92	56	68	3	99

[illegible]

S. No									Post Operative							
	4.15 Hr			4.5 Hr												
	DBP	MAP	Qua.S cale	HR	SBP	DBP	MAP	Qua.S cale	HR	SBP	DBP	MAP	Qua.S cale	Postop Recovery Time by MAS	FLACC- BPAS	Rescue analgesia and Antiemetics
1	70	80							106	104	66	79		9.25 mins	0	no
2									99	102	56	71		9.36 mins	0	no
3			3						118	108	60	76		9.04 mins	0	no
4									114	94	62	73		8.48 mins	0	no
5									128	92	56	68		8.32 mins	0	no
6									118	96	54	68		9.30 mins	0	no
7									112	98	52	67		8 mins	0	no
8									102	92	52	65		8.42 mins	0	no
9									102	94	56	69		9.38 mins	0	no
10									112	99	54	69		9.50 mins	0	no
11									112	96	54	68		9 mins	0	no
12									104	94	56	69		8.46 mins	0	no
13									94	96	56	69		9.40 mins	0	no
14									112	94	52	66		10.26 mins	0	no
15									104	94	52	66		9.48 mins	0	no
16									112	99	52	68		10.56 mins	0	no
17									99	96	54	68		9.09 mins	0	no
18									108	98	54	69		10.06 mins	0	no
19									114	94	52	66		11.05 mins	0	no
20									102	92	52	65		8.04 mins	1	t.paracetamol per rectum

GROUP-F

S. No	Name	Age Sex	Age/ Sex																										
				Basline						1min after induction					1 min after intubation					15 min					30 min				
				IP NO	HR	SBP	DBP	MAP	Qua. Scale	HR	SBP	DBP	MAP	Qua. Scale	HR	SBP	DBP	MAP	Qua. Scale	HR	SBP	DBP	MAP	Qua. Scale	HR	SBP	DBP	MAP	Qua. Scale
1	keerthana	4	2	46923	148	113	68	83		150	100	60	73		158	114	72	86		134	104	62	76	4	130	108	66	80	4
2	reginadevi	3	2	49328	129	116	67	83		121	100	60	73		138	116	74	88		140	112	71	85	4	138	110	68	82	4
3	omprakash	2	1	52946	160	118	68	85		148	110	64	79		150	112	66	81		138	116	74	88		136	116	72	87	4
4	kirthana	5	2	60187	156	112	68	83		140	110	70	83		158	116	72	87		138	118	76	90	4	136	114	72	86	4
5	anbu	2	1	35596	142	106	68	81		142	100	60	73		144	106	68	81		141	108	63	78	3	143	110	71	84	4
6	durga	2	2	35487	132	110	70	83		128	99	68	78		134	111	72	85		130	110	70	83		126	109	68	82	4
7	thiruvasan	4	1	35488	140	110	66	81		138	106	61	76		139	109	64	79		130	100	60	73	4	126	99	56	70	4
8	prasanna	2	1	55576	130	118	71			124	101	61			126	111	68			121	109	64		4	121	106	62		4
9	santhosh	3	1	54159	136	118	68	85		131	108	61	77		135	116	66	83		130	111	62	78	4	128	110	61	77	4
10	gomathi	4	2	61362	126	114	68	83		120	111	64	80		122	114	66	82		121	106	61	76	4	118	104	56	72	4
11	deepika	3	2	61124	121	118	62	81		121	111	60	77		118	114	64	81		116	111	61	78	4	116	106	54	71	4
12	mukilarasan	2	1	58462	116	109	61	77		111	99	56	70		114	100	60	73		112	99	58	72	4	111	90	58	69	4
13	saravanan	3	1	59462	124	118	68	85		119	116	62	80		126	118	66	83		124	116	64	81	4	120	111	61	78	4
14	diwakar	5	1	61650	120	99	61	74		118	98	56	70		122	109	66	80		121	106	60	75	4	116	104	60	75	4
15	sanjay	2	1	57432	118	101	64	76		116	100	62	75		124	112	66	81		121	110	61	77	4	121	101	56	71	4
16	gayathri	4	2	59652	128	111	60	77		126	99	56	70		132	114	66	82		126	110	61	77	4	124	99	58	72	4
17	nishanth	3	1	61374	131	118	68	85		130	111	61	78		134	114	66	82		132	110	60	77	4	130	109	56	74	4
18	ashwin	4	1	79876	116	101	61	74		116	99	56	70		121	109	62	78		120	101	56	71	4	116	99	56	70	4
19	durai	4	1	62459	126	111	71	84		121	110	70	83		124	114	74	87		116	111	71	84	4	118	110	68	82	4
20	prabhu	3	1	60012	124	114	66	82		120	111	64	80		126	118	62	81		122	116	62	80	4	120	111	61	78	4

S. No	Intra Operative -																													
	45 min					1 Hr					1.15 Hr					1.30 Hr					1.45 Hr					2 Hr				
	HR	SBP	DBP	MAP	Qua. Scale	HR	SBP	DBP	MAP	Qua. Scale	HR	SBP	DBP	MAP	Qua. Scale	HR	SBP	DBP	MAP	Qua. Scale	HR	SBP	DBP	MAP	Qua. Scale	HR	SBP	DBP	MAP	Qua. Scale
1	130	110	70	83	4	128	106	68	80	4	126	104	62	76	4	128	110	68	82	3	128	110	68	82	3	128	114	72	86	3
2	136	109	66	80	4	138	109	68	82	3	139	112	61	78	3	133	110	60	77	4	130	106	58	74	3	130	98	56	70	3
3	121	112	70	84	4	124	111	68	82	4	126	111	68	82	3	124	110	64	79	4	121	109	62	78	3	126	109	62	78	3
4	134	100	60	73	3	134	100	70	80	4	136	110	72	85	4	136	112	74	87	3	124	100	70	80	3	126	100	72	81	3
5	154	111	71	84	4	151	112	70	84	4	147	118	78	91	3	143	108	71	83	3	141	106	71	83	3	142	102	70	81	3
6	124	108	64	79	4	120	104	64	77	4	120	106	60	75	3	118	106	60	75	3	116	102	58	73	3	118	101	58	72	3
7	124	98	54	69	4	124	94	52	66	4	118	90	51	64	3	116	88	54	65	3	116	90	51	64	3	116	88	52	64	3
8	118	106	60		4	116	104	58		4	116	104	56		3	114	102	54		3	110	101	52		4	106	99	51		3
9	125	109	61	77	4	125	109	62	78	4	124	108	61	77	4	120	104	56	72	3	119	101	54	70	3	118	102	56	71	3
10	116	101	54	70	4	116	101	56	71	3	110	98	56	70	3	109	99	56	70	4	109	99	54	69	3	104	102	54	70	3
11	110	104	52	69	4	110	104	52	69	3	106	99	51	67	3	101	98	54	69	3	96	98	56	70	3	96	98	56	70	4
12	111	92	56	68	3	106	92	56	68	4	99	91	54	66	4	99	92	52	65	3	98	92	52	65	3	98	92	51	65	3
13	118	110	58	75	4	118	104	56	72	3	116	102	54	70	3	118	99	54	69	4	114	99	52	68	3	114	96	52	67	3
14	114	102	58	73	4	114	98	56	70	4	110	98	56	70	3	106	94	54	67	3	106	92	52	65	3	101	92	51	65	3
15	118	98	56	70	4	118	98	54	69	4	116	98	54	69	3	112	99	54	69	3	112	99	51	67	3	110	101	50	67	3
16	121	99	58	72	4	122	98	54	69	4	122	96	56	69	3	118	96	56	69	3	116	94	54	67	4	116	94	54	67	3
17	130	104	56	72	4	126	104	52	69	4	126	100	54	69	3	121	101	51	68	3	121	99	54	69	3	120	99	54	69	3
18	116	98	54	69	3	114	98	52	67	4	111	94	51	65	4	106	94	51	65	3	106	92	52	65	3	104	92	51	65	3
19	118	106	64	78	4	114	104	61	75	4	114	104	60	75	3	111	101	60	74	3	114	98	56	70	4	112	96	54	68	3
20	120	110	61	77	4	114	110	60	77	4	111	108	64	79	3	110	104	62	76	3	106	104	62	76	3	104	101	60	74	3

S. No																														
	2.15 Hr					2.5 Hr					2.45 Hr					3 Hr					3.15 Hr					3.5 Hr				
	HR	SBP	DBP	MAP	Qua. Scale	HR	SBP	DBP	MAP	Qua. Scale	HR	SBP	DBP	MAP	Qua. Scale	HR	SBP	DBP	MAP	Qua. Scale	HR	SBP	DBP	MAP	Qua. Scale	HR	SBP	DBP	MAP	Qua. Scale
1	122	102	66	78	3	114	96	57	70	3	107	86	50	62	3	109	106	68	80	3					3					3
2	126	98	54	69	3	125	96	54	68	3	124	98	56	70	3	120	100	56	71	3	111	101	58	72	3	116	104	60	75	3
3	126	108	64	79	3	124	104	60	75	3	121	104	62	76	3	120	102	61	75	3	119	102	62	75	3	118	104	64	77	3
4	126	110	74	86	3	110	100	66	77	3	108	100	65	77	3	108	102	66	78	3	102	106	68	81	3	104	104	64	77	
5	138	100	61	74	4	131	98	65	76	3	132	99	61	74	3	131	94	58	70	3	138	91	54	66	3	133	90	51	64	3
6	119	110	56	74	3	121	116	58	77	3	122	118	60	79	3	121	118	61	80	3	120	114	60	78	3	120	116	58	77	3
7	114	86	54	65	3	116	88	52	64	3	118	90	58	69	3	120	91	56	68	3	121	94	60	71	3					3
8	108	88	54		3	110	89	56		3	111	91	54		3	114	101	51		3	116	102	52		3					3
9	116	101	54	70	3	111	98	54	69	3	111	99	52	68	3	112	98	52	67	3	114	99	54	69	3					3
10	106	101	52	68	3	102	101	51	68	3	106	108	58	75	3	108	106	60	75	3	106	110	61	77	3	104	111	61	78	3
11	94	99	58	72	3	94	101	58	72	3	96	104	54	71	3	98	104	56	72	3	104	102	58	73	3					3
12	99	94	54	67	3	99	94	54	67	3	101	91	54	66	3	94	91	56	68	3	98	92	56	68	3	99	92	58	69	3
13	109	94	51	65	3	109	94	54	67	3	106	94	51	65	3	106	96	52	67	3					3					3
14	99	91	54	66	3	98	90	54	66	3	98	90	56	67	3	99	92	58	69	3	104	94	61	72	3					3
15	104	104	50	68	3	104	104	52	69	3	99	108	54	72	3	92	99	56	70	3	94	99	54	69	3	96	101	54	70	3
16	111	92	54	67	3	111	92	51	65	3	114	92	51	65	3	110	94	52	66	3	106	94	51	65	3	108	96	54	68	3
17	118	96	56	69	3	118	94	58	70	3	116	98	58	71	3	114	99	60	73	3	116	104	60	75	3	118	101	61	74	
18	101	94	51	65	3	101	91	52	65	3	102	91	54	66	3	102	94	54	67	3	99	94	56	69	3					3
19	111	96	54	68	3	114	94	51	65	3	110	94	51	65	3	109	92	56	68	3	114	98	58	71	3					
20	104	101	54	70	3	101	104	54	71	3	101	104	54	71	3	104	106	52	70	3	106	104	56	72	3	104	102	54	70	3

S. No																									
	3.45 Hr					4 Hr					4.15 Hr					4.5 Hr									
	HR	SBP	DBP	MAP	Qua. Scale	HR	SBP	DBP	MAP	Qua. Scale	HR	SBP	DBP	MAP	Qua. Scale	HR	SBP	DBP	MAP	Qua. Scale	HR	SBP	DBP	MAP	Qua.Scale
1					3					3					3						123	117	68	84	
2	119	104	64	77																	126	106	64	78	
3	118	106	68	81	3	119	111	69	83	3	121	116	72	87							118	112	68	83	
4																					106	110	62	78	
5	131	92	61	71																	120	98	64	75	
6	124	121	61	81	3					3											114	120	60	80	
7																					118	94	61	72	
8																					119	102	54		
9					3					3											119	100	58	72	
10																					108	114	61	79	
11					3					3											108	101	58	72	
12																					102	94	56	69	
13					3					3											106	96	51	66	
14																					104	94	62	73	
15																					96	102	56	71	
16	108	94	54	67	3					3											112	96	52	67	
17																					118	101	58	72	
18																					101	96	56	69	
19																					111	98	54	69	
20																					104	101	52	68	

S. No	Post Operative		
	Postop Recovery Time by MAS	FLACC-BPAS	Rescue analgesia and Antiemetics
1	9.15 mins	0	no
2	9.36 mins	0	no
3	8 mins	0	no
4	9.45 mins	0	no
5	9.56 mins	0	no
6	10.06 mins	0	no
7	10.26 mins	0	no
8	8.26 mins	0	no
9	9.16 mins	0	no
10	10.16 mins	1	paracetamol suppositories given
11	10.42 mins	0	no
12	10.46 mins	0	no
13	9.06 mins	0	no
14	10.02 mins	0	no
15	10.45 mins	0	no
16	11.02 mins	0	paracetamol suppositories given
17	9.50 mins	0	no
18	8.55 mins	0	no
19	9.50 mins	0	no
20	11.40 mins	0	no